# SECTION 8
# RISK MITIGATION: REPROCESSING

## CONTENTS

## 8 Reprocessing of reusable equipment and reusable medical devices

*"Each medical device may be used on hundreds or thousands of patients each year. As such, if there is a problem with the specific medical device that leads to infection transmission, there potentially can be a large number of patients affected."*
*Michelle Alfa, 2013 (179)*

ESTABLISH THE CONTEXT

IDENTIFY INFECTION RISKS

**ASSESS THE RISK OF INFECTION**

**CONTROL THE RISK OF INFECTION**

REVIEW EFFECTIVENESS OF CONTROL MEASURES

Reusable medical devices (RMDs) are used for diagnostic and/or treatment purpose for multiple patients and are intended by the device manufacturer for reprocessing and reuse.

This section should be read in conjunction with *Australian/ New Zealand Standard 4187:2014 Reprocessing of reusable medical devices in health service organizations* and manufacturer's instructions for intended device.

Prevention of health care associated infections (HAIs) in patients undergoing dental, medical or surgical procedures is an essential component of patient safety in the delivery of high quality health care. This section provides guidance on processes needed to effectively clean, disinfect and sterilize RMDs prior to and between patient uses. Non-RMDs e.g. toys or bedpans do have to comply with reprocessing as described in Spaulding's classification and manufacturer's instructions for use (IFU) but not as described in AS/4187.

Health Organisations (HO) are to ensure that the RMDs must be used for intended purpose or as designated by their manufacturer as suitable for reprocessing and reuse.

**AS/NZS 4187**
Reprocessing of reusable medical devices in health service organizations

NHMRC
Australian Guidelines for the Prevention and Control of Infection in Healthcare

Reprocessing refers to the activities required to ensure that a RMD is safe for its intended use. Reprocessing is a multistep process that includes cleaning, inspection and assembly, functional

testing (if applicable), disinfection (if applicable), packaging and labelling, sterilization (if applicable) and storage.

Each reusable medical device requires specific reprocessing steps or techniques appropriate for that device and many variables can impact the effectiveness of reprocessing. Factors such as device design, reprocessing methodology and methods for validating cleaning and high level disinfection or sterilization may affect the quality of reprocessing.

RMD technology is constantly evolving and reprocessing requires precision, as well as ongoing training to assure reprocessing staff competence.

- HOs should have in place quality management systems in accordance with AS/NZS 4187 (Section 2, Quality Management), Australian Commissions Safety Advisory notices and NSW policies, guidelines and Standard Operating Procedures.
- HOs should ensure that staff responsible for the reprocessing of RMDs within a facility have relevant qualifications and experience in reprocessing.
- HOs should ensure that they have the facilities, equipment, and easy access to manufacturer-specified cleaning, disinfection/ sterilization agents.
- HOs are to ensure that the manufacturers' IFUs and local procedures are followed.
- The reprocessing agents should be checked for their microbicidal effectiveness and compatibility with the device, and this should be validated.
- Appropriate PPE is to be worn by HWs when reprocessing RMDs
- HOs should only use RMDs, reprocessing agents including hospital grade disinfectants, instrument grade chemical disinfectants, sterilizing products and technologies that are listed on the Australian Register of Therapeutic Goods (ARTG) for reprocessing RMDs.
- Disinfectants and sterilizing products should only be used for their approved purpose.
- Health workers (HWs) involved in the purchase or use of disinfectants or sterilizing products should, prior to purchase, obtain a copy of the TGA listing or registration certificate (Refer to NSW Health Procurement Policy Directive).
- After reprocessing RMDs should be stored in accordance with Australian/ New Zealand Standard 4187 Section 9.5 *Handling, transport and storage of released reprocessed RMDs.*

Therapeutic Goods Order No. 54 - Standard for Disinfectants and Sterilant

Australian Register of Therapeutic Goods

HOs should have appropriate governance around the management of RMDs, suitably qualified HWs and regular audits for quality assurance to ensure risk minimisation and patient safety.

## 8.1 Reprocessing categories

The Spaulding classification system (180) classifies a medical device as critical, semi-critical or non-critical on the basis of risk to patient safety from contamination on a device. The system categorises medical equipment and devices according to their intended use and the subsequent level of reprocessing required to render them safe for reuse. Table 15 outlines these categories and includes examples of equipment and devices for each category.
Critical and semi-critical RMDs should be reprocessed in a designated reprocessing environment. However, it is not uncommon for a non-critical, usually non-invasive, RMD to be reprocessed at the point of use.

Whatever the reprocessing method may be, appropriate validation, control and monitoring of cleaning, disinfecting, sterilization and packaging is essential for reducing the transmission risk associated with the use of RMDs.

Appropriate infrastructure and resources are required to ensure effective and safe reprocessing activities, e.g. provision and validation of water and steam quality; trained and competent sterilizing technicians; and defined and documented work procedures.

**Table 25. Reprocessing categories and processes**

| Level of Risk | Process | Examples of items (Lists are not exhaustive) |
|---|---|---|
| **Critical** | | |
| A medical device that comes into contact with the vascular system or sterile tissue must be sterile at the time of use. | Clean as soon as possible after use with a detergent solution. Sterilize by moist heat after cleaning<br>If RMD is heat or moisture sensitive, sterilize using an alternative process. | Surgical instruments, diagnostic and interventional radiology catheters, cystoscopes, arthroscopes, biopsy forceps, bronchoscopes, cardiac catheters, duodenoscopes, ERCP scopes, dental hand pieces, ultrasonic scalers, cardiac and renal intraoperative probes* |
| **Semi-critical** | | |
| A medical device that comes into contact with mucous membranes or non-intact skin. | Clean as soon as possible after use with a detergent solution. Sterilize by moist heat after cleaning.<br>If RMD is moist heat sensitive use a low temperature sterilization process or thermal disinfection or disinfection using a high level instrument grade chemical disinfectant. | One-way breathing valves, pneumotachograph screens, mouth shutters, respiratory/sleep therapy equipment, laryngoscope blades, vaginal ultrasound transducers, colonoscopes, gastroscopes, nasoendoscopes and specula. |
| **Non-critical** | | |
| A medical device that only comes into contact with intact skin and not mucous membranes | Clean as soon as possible after use with a detergent solution. If necessary, disinfect with compatible low-level or intermediate-level disinfectant after cleaning. | Bedpans, commodes, EEG and ECG leads, blood pressure cuffs, beds, thermometers, SaO2 probes and stethoscopes. |

* Intraoperative probes that will have contact with sterile tissue or the vascular system.

## 8.2 Reprocessing methods

In accordance with AS/NZS 4187, the three usual methods for reprocessing are defined as:

- **Cleaning:** The removal of contamination from an item to the extent necessary for further processing or intended use.
- **Disinfection:** Reduction of the number of viable microorganisms on a product or item to a level previously specified as appropriate for its intended further handling or use.
- **Sterilization:** A validated process used to render a product free from viable microorganisms.

### 8.2.1 Cleaning

Reprocessing begins with processing at the point of use i.e., close proximity to the point of use of the device to facilitate subsequent cleaning steps. The point-of-use processing, includes prompt, initial cleaning steps and/or measures to prevent drying of soil and contaminants in and on the device.

Thorough cleaning and removal of visible soil by manual or automated systems is essential for both disinfection (thermal or chemical) and sterilization of RMDs, as residual soil (organic or inorganic) on the RMD surface can interfere with the effectiveness of these processes.

Instruments are to be cleaned either by hand and/or mechanically, following both manufacturer's instructions and the requirements set by AS/NZS 4187 to assist with identifying the level of reprocessing required.

If the device has removable parts, then reprocessing instructions must include step by-step instructions for disassembly and reassembly of the device to facilitate cleaning and reprocessing. The equipment needed to perform these activities must be identified and provided to HWs performing these tasks. For easy access to information diagrams, photographs, illustrations and/or videos on manufacturer's IFU are recommended. In addition, the instructions should indicate the location where this step should be performed (e.g., at the point of use, at the designated cleaning area).

Disassembly and reassembly instructions must be explicit, device-specific, and concurrent with the validation activities. The HWs performing these tasks must be trained and qualified in the processing of RMDs. The cleaning process must be validated and at a minimum by visual inspection.

For cleaning of RMDs, IFU often recommends a neutral or near-neutral pH detergent solution because such solutions generally provide the best material compatibility profile and good soil removal. Enzymes, usually proteases, sometimes are added to neutral pH solutions to assist in removing organic material by attacking proteins that make up a large portion of common soil (e.g. blood). Enzyme solutions should be used in accordance with manufacturer's IFU, which include proper dilution of the enzymatic detergent and contact with equipment for the amount of time specified on the label.

The cleaning process should flow in one direction from dirty/contaminated to clean and, ideally the reprocessing of the RMDs should be in a dedicated area if not well clear of the contaminated zone.

### 8.2.2 Disinfection

Disinfection (thermal or chemical) of RMDs kills many pathogenic microorganisms. However, unlike sterilization, disinfection is not effective against high numbers of bacterial spores. Many factors affect the efficacy of a disinfecting process i.e. presence of soil, nature and level of microbial contamination, RMD design, concentration of disinfectant, temperature and exposure time, pH levels and presence of biofilm. Therefore, users should read labels carefully to ensure the correct product is selected for the intended use and applied to meet maximum efficacy.

NSW Health Safety Notice 001/14
Use of Impregnated Chemical Disinfectant Wipe Systems for Reusable Medical Devices

Chemical disinfectants vary significantly in their antimicrobial abilities and speed of action. Specifically:

- Low-level disinfectants: kill most vegetative bacteria (except *Mycobacterium tuberculosis*), some fungi and inactivates some viruses.
- Intermediate-level disinfectants: kill vegetative bacteria including mycobacterium species, viruses and all fungi and inactivates most viruses but do not kill bacterial spores.
- High-level disinfectants: kill all microorganisms with the exception of high numbers of bacterial spores. Some disinfectants used as high-level

Therapeutic Goods Order No. 54 - Standard for Disinfectants and Sterilant

World Health Organization Laboratory Biosafety Manual 3rd edition, 2004

disinfectants are capable of sterilization with prolonged exposure, under controlled and defined conditions.

RMDs that requires exposure to a disinfecting process must have been categorised as semi-critical or non-critical according to Spaulding classification (AS/NZS 4187).

- Semi-critical RMDs must be sterilized by either validated moist heat or low temperature sterilizing process between uses on individual patients unless RMD is not compatible with these processes.
- Semi-critical RMD that is not compatible with sterilization must be subject to a validated thermal disinfection process between uses on individual patients unless RMD is not compatible with this process
- Semi-critical RMD that cannot withstand thermal disinfection process must be subject to a validated high level chemical disinfecting process between uses on individual patients.

### 8.2.3 Sterilization

Sterilization destroys all microorganisms on RMDs, rendering them free of viable microorganisms. There are several forms of sterilization and the selected method must be recommended by the RMD's manufacturer.

Moist heat sterilization is the preferred process of sterilization of RMDs where the item can withstand the high temperature and pressure of this process. If an item cannot withstand a moist heat sterilizing process, a suitable and alternative validated process will be necessary.

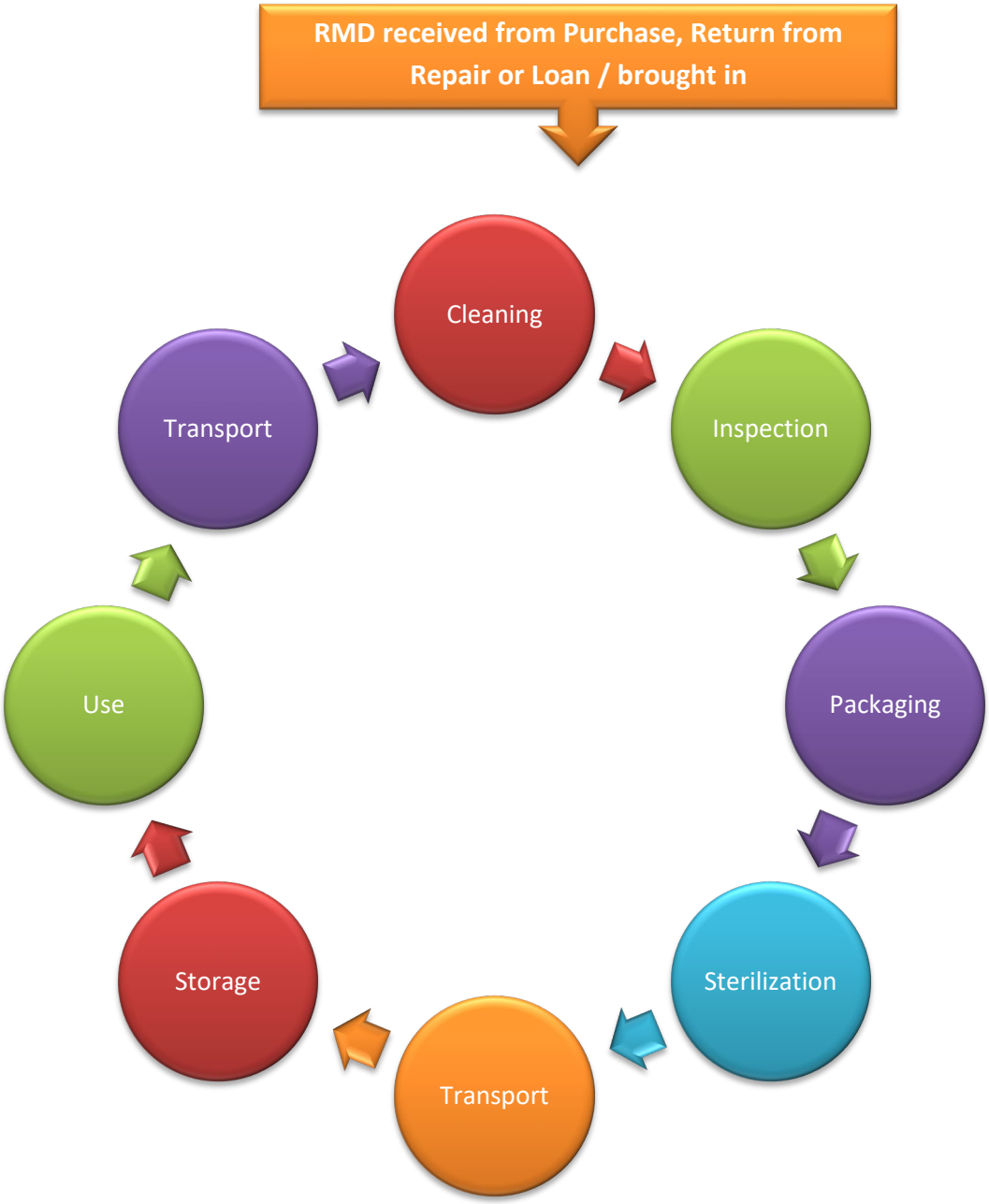
An alternative form of sterilization may be a low temperature gas, plasma or liquid chemical sterilizing process and may also depend on resources available within the HO.

The delivery of sterile products for use in patient care depends on the effectiveness of the sterilization process including the unit design, decontamination, disassembling and packaging of the device, loading the sterilizer, monitoring, sterilant quality and quantity, and the appropriateness of the cycle for the load contents, and other aspects of device reprocessing.

Ensuring consistency of sterilization practices requires a comprehensive program by HOs that ensures operator competence and proper methods of cleaning and wrapping instruments, loading the sterilizer, operating the sterilizer, and monitoring of the entire process.

## 8.3 Reprocessing critical items

***Figure 5 Reprocessing of a critical RMD should involve the following steps:***




**Note: Follow Instruction for Use as per supplier specifications at each step**

## 8.4 RMDs on loan on brought by clinicians

With the ever increasing complexity and cost of medical procedures and surgical instruments in general, it has become impossible for every facility to own every type of equipment. Loan sets have become an integral part in the care of patients requiring surgical intervention, as public health organisations, rather than purchasing instrument sets, increasingly utilise loan sets of instruments.

In the decision making process regarding use of loan sets, privately owned RMDs and/or RMDs brought in by clinicians, HOs should identify:

- Key stakeholders and their roles and responsibilities, local governance and accountability
- The financial and resource implications, including the capacity to accommodate the volume, complexity, storage and resources required for reprocessing,
- HOs must always check for approval for use in Australia, ARTG certificate, manufacturers IFU, local procurement processes and biomedical engineering requirements

- The supply, packaging, transportation, handling and processing of loan sets must be undertaken in a manner that ensures the safety of patients and HWs involved and comply with occupational health and safety regulations.
- All loan transport containers must comply with WorkCover regulations and should be maintained by the supplier in a clean, dry state. In addition, should be in good working order. The HO needs to have a system in place for handling loan equipment that complies with WorkCover regulations[i].
- The medical team should provide the designated HWs with a full description of the RMDs required to be ordered on loan
- HWs must provide all instructions necessary for the provider to supply the loan sets in a manner that is safe and timely, and allows for sufficient time for reprocessing the loan instruments.
- The scheduling of procedures may be influenced by whether additional reprocessing, education and training requirements need to be met prior to or after reprocessing and the duration of reprocessing required.
- Prior to use loan sets must undergo cleaning and disinfection or sterilization as appropriate for the intended use. This applies to instruments and equipment loaned by sponsors and other health organisations e.g. Loan Sets, Borrowed RMDs from private facilities and RMDs used between public facilities, as well as instruments and equipment owned or supplied by individual staff including locums, visiting medical officers and staff specialists.
- Prior to reprocessing HWs must inspect loan set instruments against the supplier documentation of contents on arrival and on return to confirm that the contents are correct and complete and that all appropriate documentation (i.e. tray lists) is present. HW must also check that the manufacturer's IFU and local procedures for reprocessing are provided and followed.
- Suppliers must send disassembling, cleaning and sterilization/disinfection instructions for multi-component instruments and these instructions should be followed.
- HW must ensure that the reprocessed loan sets are delivered for use on time and with all required documentation. Perceived lack of time should not permit the cleaning process to be bypassed.
- After use, and before being returned, loan sets must be cleaned and disinfected, sterilized or thermally disinfected as per the IFU. Any damaged instruments or instruments needing repair should be reported to the provider. Any instruments missing should be reported immediately to the operating theatres. The notification should comply with the NSW Health Incident Management Policy.
- Reusable loan set instruments used on humans must never be used on animals, or for necropsy or autopsy.

Where a HO is expected to reprocess clinician owned RMDs or loan sets, the HO's reprocessing unit is to be provided with the following information when receiving the device/sets:

- Manufacturer's name
- Name and contact details for manufacturer's local representative
- ARTG certificate or list number
- Device manufacturer's IFU
- Time requirement for reprocessing, identified risks and control measures if any; and specific training if needed

Without the provision of this information, local reprocessing units will be unable to adequately reprocess privately owned RMDs or loan sets.

To reduce the risk of damage to privately owned RMDs or loan sets during transit to the HO, instrument containers should be fit for purpose, packaged and transported in a way that prevents damage; and meet the requirements for manual handling of the Work Health and Safety Regulation 2011.

Work Health and Safety Regulation 2011

On receipt at the HO, the local reprocessing unit should examine the integrity of the container. If the integrity of the container has been compromised, then the following actions are required:

Management of Instruments, Accountable Items and Other Items used for Surgery or Procedures

NSW Health Incident Management Policy

- Decant contents of broken container into an intact container
- Remove the broken container from circulation
- Reprocess instruments, regardless of whether the contents have been previously reprocessed
- Report issues to the sponsor and the TGA.

### 8.5 Implantable devices

- Devices or items intended for human implantation must not be reprocessed or reused after patient use.
- Implantable devices must not be 'flash' sterilized.
- Implantable devices used for orthopaedic and dental surgery that are received packaged and sterilized with identification from the manufacturer, should not be opened and used to restock racks or trays.
- The implantable devices manufacturers to provide validated cleaning instructions that clearly state whether implantable screws and plates can be reprocessed or not (181).
- The implantable devices labelled as "single use" are not to be reprocessed.
- Complete documentation as per NSW Health Care Records - Documentation and Management

Health Care Records - Documentation and Management

## 8.6 Management of incidents

HOs that undertake reprocessing of RMDs must have an established system in place to manage incidents of real or suspect cleaning, disinfection or sterilization failure.

If any item(s) used on a patient are subsequently found to be unsterile or inadequately disinfected, the health organisation must determine the extent of the problem. A risk assessment framework must be used to determine infection control breaches related to sterilization or disinfection failure. Processing failures relating to items used in patient care must be investigated and managed in

accordance with current AS/NZS 4187, Infection Prevention and Control Policy Directive section 4 and Incident Management Policy Directive.

Effective management of the recall process requires the traceability of RMDs to patient records by either electronic or manual system.

Where the processing equipment has failed, the equipment under question must not be used again until rectified and satisfactory results are obtained from physical, chemical and/or biological monitoring.

When the processing equipment has been repaired and or rectified, physical and chemical monitoring to be conducted to confirm if the equipment is fit for reuse.

## 8.7 Management of complex and difficult to reprocess RMDs

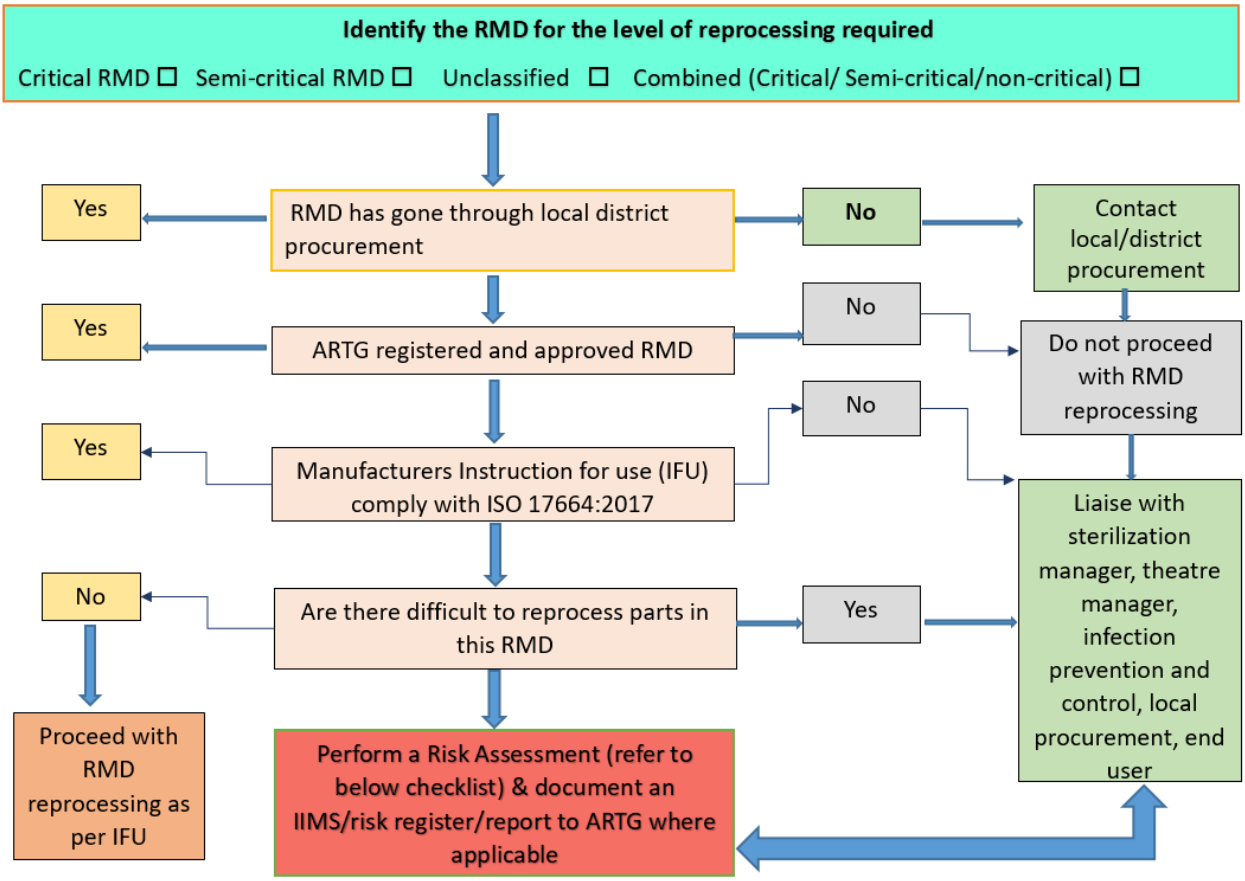
Reusable RMDs are designated as difficult to reprocess when the effectiveness of the cleaning, disinfection or sterilization process cannot be guaranteed.

- To guarantee effective cleaning, the design of the device must allow friction to be applied to all surfaces either by brushing or ultrasonic action and also allow visual inspection of those surfaces.
- Dead-ended lumens must be considered as difficult to clean RMDs,
- Reprocessing facilities, perioperative services and facilities with procedure rooms should work towards replacing all complex and difficult to reprocess RMDs with items that can be dismantled for ease of cleaning and reprocessing.
- Keep a list of RMDs that are difficult to reprocess and document in the risk register.

HOs must adopt a comprehensive risk management approach when making decisions about purchasing, hiring or borrowing medical instruments and equipment to reduce the risks associated with difficult to reprocess RMDs. Refer to Figure 6 and table 26 for further details on risk assessment.

**ISO 17664:2017**
Processing of health care products — Information to be provided by the medical device manufacturer for the processing **of medical devices**

*Figure 6. Risk assessment Flow Chart*



### Table 26: Risk Assessment Checklist for RMDs when IFU does not comply with 4187 or RMD identified as difficult to clean

☐ IFU does not comply with 4187 ☐ RMD identified as difficult to clean

Name of the RMD……

Manufacturer ……

Liaise with the following stakeholders to proactively conduct comprehensive risk assessment using the below checklist.

☐ Sterilization Services team ☐ Infection Prevention and Control team

☐ Procurement (local/district) ☐ End users (e.g. surgeon, Theatre manager)

☐ Other (……)

| | Yes | No | N/A |
|---|---|---|---|
| Are there alternative methods available for the RMDs to be reprocessed according to AS/NZ 4187: 2014 to a safe level which minimises infection risks to patients? | | | |
| If the answer to the above question 'no', consideration must be given to the following: | | | |
| Is the RMD able to be substituted with a more suitable device? | | | |
| Is there a single use option available for this RMD? | | | |
| Is the use of this RMD necessary at the facility? | | | |
| Is the non-use of this RMD life threatening to the patient? | | | |
| Review the device's IFU to identify:<br>o Is it a complex item?<br>o Is there correct tools available to assemble/reassemble this RMD?<br>o Is there correct solutions available to reprocess this RMD?<br>o Is there enough inventory to allow for adequate turn-around time to effectively reprocess the device | | | |
| Whether parts and/or the whole device can be sterilized? | | | |
| Is there a need for sterile sheath/cover? | | | |
| Is there a need for any process change to reprocess this RMD? | | | |
| Are there risk mitigation strategies able to be implemented to reduce infection control risks to patients? | | | |
| Staff responsible for reprocessing RMDs are trained to perform all reprocessing steps as per the device's IFU | | | |
| Is the risk mitigation strategies implemented and documented? | | | |
| Is there a need for this RMD to be reported to ARTG? | | | |
| Have you contacted your peer group for input to establish if device use is wide-spread or isolated? | | | |
| Incidents of surgical site infections or adverse events associated with procedure or this RMD use has been recorded and reported? | | | |

**Comments**:

……

……

Name …….. Designation ……..

Date of assessment…… Signature ……

## 8.8 New technologies

New technologies have made great advancements with beneficial outcomes for patients requiring specialised and complex surgical procedures. Extensive consultation with the reprocessing unit and infection prevention and control is required prior to the purchase of any new technologies.

A risk assessment of the RMD may be required, particularly if the instrument is deemed to be 'difficult to reprocess' (refer to figure 6 and table 26 for further information).
The assessment should consider:

- The design of the instrument
  - Can it be taken apart for thorough cleaning?
  - Are there any complex joints that cannot be cleaned adequately?
  - Will the design affect the ability to clean over time?
- Local capacity and expertise
  - Can optimal and validated reprocessing of this instrument be done in this unit?
  - Is this unit equipped to reprocess this instrument?
  - Do reprocessing staff need specific training to reprocess this instrument?

Risk assessment outcomes should be reported to the appropriate Clinical Governance delegate for further discussion with the HO's product selection committee or equivalent.

Section 2.4.1
Purchasing new equipment

When new instrumentation is purchased, the HO should ensure that the manufacturer or their representative provides initial training to HO staff. Once initial training has been provided, local trainers are responsible for providing education to other staff members, including new staff.

## 8.9 Reprocessing in Oral health

The practice of dentistry frequently involves the use of sharp instruments which can pierce skin and mucous membranes during treatment. In dental practice there is a risk of cross-contamination as treatment may involve contact with saliva, blood and endodontic pulp tissue(1). These and other dental materials may be difficult to remove if allowed to dry.

Australian Dental Association
ADA Infection Control Guidelines

NSQHS Standards Guide for Dental Practices and Services

Effective sterilization of instruments relies on effective cleaning prior to sterilization. Therefore, all visible dental materials should be removed from instruments at point of use to prevent substances drying on these instruments. Formal training in reprocessing of RMDs is required for all personnel who clean and reprocess dental equipment.

Many of the reusable instruments and burs utilised in oral health services are classified as 'difficult to reprocess' and require special attention and cleaning procedure. Refer to the flow chart (Figure 6) Table 26 for further information on risk assessment on difficult to reprocess RMDs.

Oral health services utilising a steam sterilizer to sterilise dental equipment within their unit are to follow the requirements for testing, documentation and quality control as specified by AS/NZS 4187.

The Dental Board stipulates the expectations for infection prevention and control based on the current edition of the ADA's Guidelines for Infection Control and NHMRC Guidelines, plus current versions of either AS/NZS 4815 or AS/NZS 4187 for instrument reprocessing. Where AS/NZS 4815 is applied units are to detail rational and compliance for the standard and would benefit on conducting GAP analysis between AS4815 and AS4187.

When RMDs are being reprocessed outside of the oral health service unit, contaminated RMDs are to maintain moisture to prevent from possible debris drying on instruments. These items must be contained within a puncture-proof and lidded container for transportation and the transport vehicle should be temperature controlled. HOs must have a formalised and documented process for delivery and pick-up of instruments.

Surface barriers help prevent contamination of surfaces and equipment. Surface barriers on equipment need to be placed carefully to ensure that they protect the surfaces underneath and should be changed and cleaned between patients. Cleaning clinical surfaces including equipment should always occur between patients or uses, regardless of whether a surface barrier has been used or not, any exceptions should be justified by risk assessment) NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare).

For specialised equipment which is difficult to clean and the application of detergent directly onto the device is not recommended by the manufacturer, a custom surface barrier should be used e.g. intraoral camera. Any custom surface barrier used on such equipment should be disposed of after each patient treatment and replaced with a new custom surface barrier.

The custom surface barriers are specific to each type of specialised equipment, and provided by the manufacturer of that specialised equipment. HOs must not use other surface barriers on that specialised equipment.

HOs should have a local policy that describes their specialised equipment and its specific reprocessing.

## 8.10 Maintenance and repair

RMDs that are to be sent for maintenance or repair must, prior to dispatch be cleaned and disinfected or sterilized in accordance with the manufacturer's IFU.

On return prior to placing back into circulation for use, these items must be reprocessed in accordance with manufacturer's IFU and facility procedures.

## 8.11 Covers and Sheaths

Some RMDs may require a single-use sterile cover or a sheath to protect the instrument or equipment during procedures. When covers or sheaths are used the reusable item(s) must be completely reprocessed between patient procedures.

Covers and sheaths must not be used as a substitute for routine cleaning, disinfection or sterilization of instruments and equipment.

## 8.12 Reprocessing semi-critical items

### 8.12.1 Intracavity ultrasounds

Intracavity ultrasound transducers (e.g. transvaginal, trans-rectal/TRUSS or intraoperative) are to be reprocessed in accordance with the manufacturer's IFU and AS/NZS4187. If an intracavity ultrasound transducer cannot be sterilized, thermal or high level chemical disinfection is required to minimise the risk of cross contamination and ensure patient safety (182). Additionally, automation, validation, and traceability of disinfection systems for ultrasound probes are recommended.

Sterile gel and sterile probe covers should be used.

**NSW Health Safety Information 001/14**
Correct Usage of Fume/Vapour Soaking Stations

**ASUM-ACIPC**
Guidelines for Reprocessing Ultrasound Transducers 2017

The use of disposable/sterile covers are not used as a substitute for cleaning, disinfection or sterilization.

Fume extraction cabinets may be required while using the recommended chemical disinfectant.

Specialised requirements are to be followed when disposing of chemical disinfectants.

Approved spill kits are to be available in the reprocessing area in case of spillage of the chemical disinfectant.

Appropriate PPE is to be worn by HWs when reprocessing ultrasound transducers.

Reprocessing cycle records are to be maintained by the HO with the following information as a minimum:

- transducer serial number;
- date and staff members responsible for reprocessing;
- method of disinfection; disinfection cycle or load number;
- name and signature of the person releasing the transducer for use.

If using chemical disinfection, batch information, preparation date and use by date of the chemical disinfectant should be documented.

- Any failed cycles or interruption during the disinfection process are to be documented and the transducer must be fully reprocessed prior to use. In addition, chemical indicators are to be used to validate concentrations and/or holding time and documented as recommended by the chemical disinfectant manufacturer.
- To ensure HW safety and reduce the risk of damage, contaminated ultrasound transducers are to be transported to the reprocessing area immediately after use, in a closed container that can be effectively cleaned.
- Transport containers are to be thoroughly cleaned and dried between uses.
- Reprocessed ultrasound transducers are to be stored in a clean environment to maintain the sterilization or disinfected process.
- Each sterilized or disinfected ultrasound transducer is to have an indicator attached to confirm that appropriate reprocessing methods have been followed.

### 8.12.2 Reprocessing flexible endoscopes

Flexible endoscopes invariably become contaminated with microorganisms during clinical use. With more widespread use of flexible endoscopes cross infection involving oesophago-gastroduodenoscopy, colonoscopy, endoscopic retrograde cholangiopancreaticography (ERCP), or bronchoscopy have been observed and described in many countries.

Despite the use of standard cleaning and disinfection techniques required to decontaminate endoscopes, infection prevention and control breaches have been reported. This is mainly due to the complex design of channels and valve systems within endoscope. Therefore, HOs should have a reliable, high-quality system for endoscope reprocessing to minimise transmission of pathogens to patients during endoscopic procedures. Likewise, HOs should have an infrastructure that supports training and competencies, quality measurement and management program for endoscope reprocessing.

HOs should ensure the following critical steps are followed when reprocessing flexible endoscopes:

- Identify brand and model for each endoscope.
- Obtain the manufacturer's IFU for all brands and models.
- Understand the manufacturer's IFU for cleaning each endoscope.
- Be aware of the number of channels and valves within the endoscope.
- Adhere to the manufacturer's IFU for reprocessing.
- Check compatibility of scope IFU and automated Endoscope Reprocessor (AER) IFU.
- Evaluate the reprocessing procedures.
- Document the process to enable traceability.

**GESA**
Position Statement – March 2017: Infection Control in Endoscopy

**NSW Health Safety Notice SN: 002/06**
Cleaning of flexible endoscopes (reprocessing)

### 8.12.3 Infant feeding equipment

Before use by another baby, reusable baby bottles, teats and caps must be cleaned and thermally disinfected in accordance with the manufacturer's IFU.

Breast feeding equipment, such as breast pump components, must be cleaned and sterilized between patients.

Chemical disinfection must only be used on equipment that is designated to and reused by one baby.

Prior to transfer, staff should provide guidance to parents or carers about cleaning and disinfecting feeding equipment that is appropriate for the home setting.

## 8.13 External ultrasounds

RMD, including bladder scanners, ultrasound machines and transducers may act as both a source and a vector of potential cross contamination.

Under certain unfavourable circumstances ultrasound gel can also become contaminated with a variety of microorganisms and can cause infection.

An ultrasound probe used on intact skin is classified as non-critical equipment. After use it requires cleaning, as per the manufacturer's IFU and depending on the outcome of a risk assessment, low level disinfection with an approved and compatible disinfectant.

### 8.13.1 Surface probes used on intact skin and bladder scanners

Following a non-invasive procedure, e.g. scanning over intact skin or bladder scan, all gel is to be removed from the probe and the transducer probe is to be cleaned with a neutral detergent non-residual wipe and, if required, disinfected with an appropriate hospital grade disinfectant in compliance with the manufacturer's IFU and TGA regulations.

After use the cleaning procedure should include the entire cable from the transducer to the machine and extend to the surface of the machine.
If an ultrasound transducer or associated equipment comes in contact with blood and/or body fluids, first clean with a neutral detergent and then disinfect with an appropriate disinfectant in compliance with the manufacturer's IFU and TGA regulations.

### 8.13.2 Ultrasound devices used on non-intact skin or contact with mucous membrane

Ultrasound transducers used for imaging the vascular system for insertion of venous access devices should be used with a sterile probe cover and sterile gel.

If the probe cable is likely to come into contact with a sterile drape, e.g. during insertion of a central access device, the cable should be covered with a long sterile sheath and be managed in such a way as to maintain the sterility of the procedural region.

Following use, the cable cover is to be removed without contaminating the surface of the cable or the ultrasound machine. After use it requires cleaning, as per the manufacturer's IFU and, depending on the outcome of a risk assessment, high level disinfection with an approved and compatible disinfectant.

The probe/transducer must be cleaned and disinfected as per IFU and risk assessment regardless of the use of sheath/cover

After cleaning, all transducers must be stored in an appropriate environment to protect from environmental contamination. It is recommended that a specific cabinet is used, but if this is not available the minimum standard recommended is a clean disposable cover applied to the transducer to mitigate risks from environmental contaminants.

Records of reprocessing must be kept in accordance with the requirements specified in AS/NZS4187 and manufacturers IFU to ensure a system of traceability is in place to enable recall procedures to be followed in case of decontamination failure.

### 8.13.3 Light based disinfection systems for use with ultrasound probes

Light based disinfection systems (LBDS) are listed on the Australian Register of Therapeutics Goods (ARTG) as Class IIB medical devices. An Advisory (A19/02) was released by the Australian Government, Department of Health: Diagnostic Imaging Accreditation Scheme in 2019 to provide guidance on the requirements for using this type of disinfection method. Before purchasing light based disinfection systems for ultrasound probes, the following is recommended:

- Determination if the device (e.g. ultrasound probe) is compatible with the light based disinfection system (LBDS).
- Determination if the LBDS is registered with TGA.
- The manufacturer of LBDS provides evidence for microbial reduction/antimicrobial efficacy.
- The manufacturer provides device specific IFU.
- Determination of any treatment of RMD that is required prior to exposure to the process to ensure its effectiveness.
- Determination of any restrictions or limitations relating to the size, mass, configuration, or loading orientation of RMDs being processed.
- Review of current evidence related to the light based disinfection systems.
- Risk assessment of physical location for the LBDS to determine reprocessing workflow, storage requirements and maintenance
- Determination on how the ultrasound probes will be tracked, location of the record storage and in the patients record.
- Documented procedure for reprocessing, including PPE requirements.
- Approval to purchase and use the LBDS by local Infection Prevention and Control team and Central Sterilizing Manager and local procurement.
- Program for staff training and competency assessment for reprocessing ultrasounds.

- Will you be able to validate the LBDS to comply with AS/NZS4187?
- How will this improve the current system for reprocessing of ultrasounds?
- What is the Spaulding classification level for the ultrasound to be reprocessed and will this system provide the correct classification
- Will there be additional consumables and costs associated with using this system?
- What will the routine monitoring include and who will have responsibility for completing and documenting this?
- Will using this system impact on any other workflow or service provision?
- Has the risk verses' benefit been determined for patient safety?

## 8.14 Stethoscopes

Auscultation of the heart, lungs, abdomen, and major arteries with a stethoscope has long been considered an integral part of the physical examination and most clinicians prefer to use their own stethoscope (183). Evidence suggests that stethoscopes are potential vectors for microorganism transmission between patients (184, 185). *S. aureus* has been identified surviving on ear pieces of stethoscopes for longer than 18 hours (186). All parts of the stethoscope that have been in direct contact with skin (patient's or clinician's) should be cleaned before reuse. In extreme risk clinical areas, or during outbreaks, HWs should consider using Single Patient Use stethoscopes (183).

## 8.15 Toys

Toys are potential vectors for fomite transmission and are reservoirs for microorganisms (187, 188). Toys and items that are handled, placed in children's mouths or used in baths are to be washable, quick drying and easy to clean. HO should not purchase or encourage the use of water-retaining bath toys, non-washable soft toys and other toys which are difficult to clean. If such toys are brought into the HO by the patient or their visitors, use should be limited to a single patient only.

NHMRC
Staying Healthy: Preventing infectious diseases in early childhood education and care services
(5th edition)

Used toys and therapeutic aids should be cleaned between each patient with a neutral detergent. If toys or therapy items become contaminated with body substance including saliva, by actions such as sneezing or putting into a child's mouth, remove from use until washed in warm water and detergent and dry. Should it be required, dry cleaning instructions for the toy should be discussed with the patient and/or carer. If a toy cannot be cleaned it should be discarded.

Soft toys should not be permitted in a communal area unless the toy is being used as a therapeutic aid for an individual patient. Clinicians who use soft or otherwise 'difficult to clean' toys as therapeutic aids should consult with local infection prevention and control team and undertake a documented risk assessment for the selection, maintenance and cleaning of these items.

## 8.16 Cleaning and reprocessing of items used in community and home settings

Where possible, a HO should provide HWs with disposable sterile equipment as this will minimise the need to transport contaminated equipment and subsequent reprocessing. Disposable single-use equipment should be disposed of after use.

Reusable equipment that can be reprocessed must be reprocessed in accordance with the manufacturer's IFU and local policy.

## 8.17 Reusable Portable equipment

The following practices are recommended regarding cleaning and reprocessing of reusable portable equipment in community and home settings:

- A risk assessment for selection of portable items is to be undertaken by the HW.
- Portable reusable materials and equipment e.g. equipment bags, weight scale, chair pads, examination mattresses, laptops or IV volumetric pump/pole, used in the provision of patient care are to be:
  - easily cleanable
  - routinely cleaned at regular intervals in accordance with manufacturer's IFU and/or health service recommendations
  - cleaned after use and between patients
  - removed from use if worn or damaged

  **Other Considerations**:
  - Do not take unnecessary equipment into the area, or
  - Use a protective sheet between the equipment and the surface
  - Clean and, if necessary, disinfect equipment on removal from the room
- Equipment provided to clients for use at home e.g. commodes, chairs, heel protectors, pressure relieving cushions, are to be:
  - Non-porous, fluid repellant and fully washable, or
  - Single patient use
- The HO is to have a program for ensuring that loaned equipment is cleaned and, if necessary, disinfected when it is returned from clients' homes.

## 8.18 Transport of RMDs and Equipment

RMDs should be transported in designated transport system/containers that are of adequate size to contain the RMDs safely and are to be securely closed and the containers can be easily cleaned and disinfected.

The transport system/containers should be clearly labelled to identify the contents and should be disposed of when no longer serviceable.

If transporting contaminated semi-critical or critical RMDs is necessary, the RMDs are to be confined and contained within single use a leak-proof plastic bag. The bag should then be placed in a rigid reusable container that is secured within the vehicle, and separated from the driver's compartment. The RMD and equipment should be reprocessed in accordance with IFU and local facility guidelines.

Contaminated RMDs/equipment and unused sterile equipment should not be transported in the same container.
Personnel responsible for packaging, transport and the collection of the used RMDs should be trained to do so.

When transporting reprocessed RMDs the following items should be considered:

- Where possible temperature and humidity monitoring of sterile stock while in transit is recommended including maintaining records of the information. For short transport a climate controlled vehicle is recommended.
- Mechanical cleaning of all the transport containers after transport of dirty items and before transportation of sterile stock.
- External labelling of container and securing methods to prevent unauthorised access to contents.
- The use of sealed dust covers for transportation of all sterile stock.
- Minimum requirements for the fit out of transport vehicles i.e. physical separation of sterile and dirty stock etc.

- Transport vehicle guideline in regard to breaches in parameters in transit/ in the event of an accident where stock has been compromised.
- Ensuring there is insurance in place if the transport vehicle is involving in an accident destroying the load

Where problems have been encountered during transport and storage of a reprocessed and released RMD recall and risk assessment of the RMD is necessary.

## 8.19 Stock room for RMDs/ sterile equipment or consumables

Sterile items including RMDs sterilized in the healthcare facility and sterile items produced from commercial suppliers shall be stored and handled in a manner that maintains the integrity of packs and prevents contamination from any source. A dedicated and controlled storage area shall be provided for the storage of RMDs and sterile consumables (30).

- The planning of stock storage areas and systems is integral in ensuring efficiency and that the sterile stock maintains its integrity, is fit for purpose and safe for patient use.
- The storage area should have suitable materials with smooth finishes, non-sheading, water resistant and robust enough to withstand frequent cleaning
- The floor surface should be impervious, have adequate drainage and be easy to clean.
- Lighting should be fitted flush into ceiling to reduce dust entrapment
- Bulk storage area should be located on the periphery of the unit so that deliveries of commercially prepared sterile stock is deboxed from outer store/transportation packaging before being brought into the sterile stock storage area. Space is needed to unpack cartons.
- Sterile storage area is not to be used as a shared equipment storage space (e.g. wheelchairs etc.)
- Sterile stock storage area should be constructed to ensure there is no risk of sterile stock coming into contact with water.
- In storage areas, temperatures should be controlled within the range of $18^0$C to $25^0$C and supplies should be protected from direct sunlight.
- Appropriate air handling systems and heat / moisture management with a relative humidity of 35% to 70% is recommended.
- All items stored on open shelving units should be stored at least 250 mm  off the floor and 440 mm from the ceiling
- Once RMD have been reprocessed, items should be returned to the point of use.
- Sterile RMD and sterile consumables should be stored on or in designated shelving or containers.
- Access to the storage area must be restricted to staff that have received training and are deemed competent in handling RMDs
- RMDs must be handled in a manner that does not cause contamination of the contents or damage to the Sterile Barrier System.
- Sterile store areas must be regularly cleaned to a routine, documented schedule

## 8.20 Event-Related Sterility

The shelf-life of a packaged sterile item is event-related and depends on the quality of the sterile barrier system (wrap, pouch, and container), the storage conditions, conditions during transport, and the amount of handling.

Certain events compromise the sterility of a package. These events include multiple handlings, moisture penetration, and exposure to airborne contaminants, all of which can compromise the integrity of the packaging and seal and allow contaminates to enter the packaging.

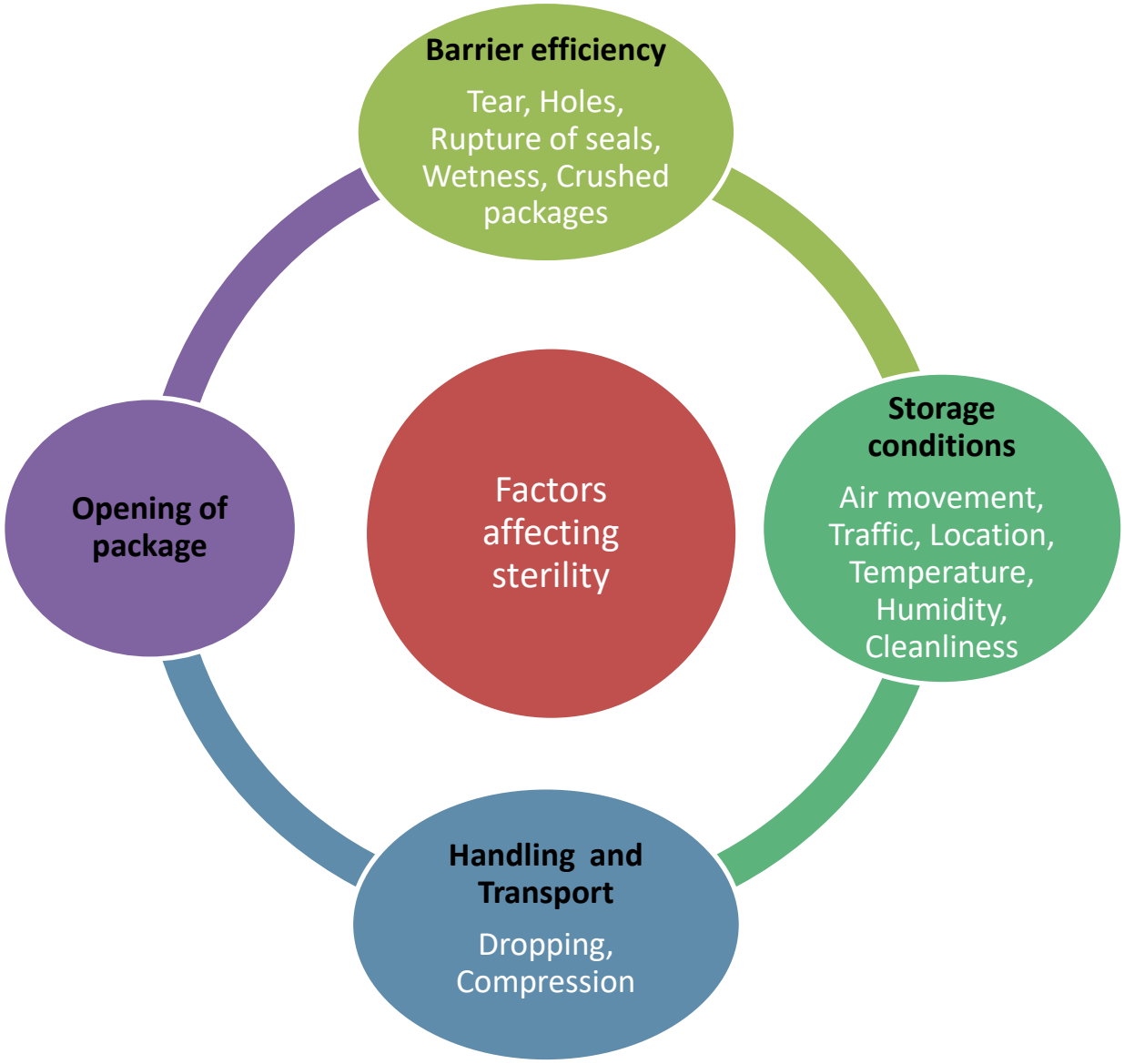
Association for the Advancement of Medical Instrumentation (AAMI) ST79 Section 10.3.3 states that event-related dating can be used unless the product has an identifiable expiration date because of the degradation of the product based on information from the device manufacturer. The wraps and pouches manufactures should provide evidence to confirm the duration of product integrity and product specific expiry date and the IFU should be referenced as per AS 4187.

To practice event-related sterility, a healthcare organisation needs to control handling from the time the item is removed from the sterilizer to transportation, storage and patient use.

- HOs should have written procedures for how shelf-life is determined and risk assessment approach should be applied in the event of a potential breach.
- HOs to ensure that sterile stock is stored according to the date of manufacture, with older stock to be used first.
- Inspect all sterile items prior to use to ensure the integrity of the packaging, chemical indicator change, and condition of the item.
- Return compromised sterile items to the appropriate personnel so that protocols related to the management of these items may be implemented.

Figure 7 should be used as a guide to determine the event related sterility of an item.

*Figure 7 Factors affecting sterility of a reprocessed item*




### 8.20.1 Risk assessment in the event of sterility compromise

In the event of potential contamination within the sterile stock areas/room due to breakdown or issue with air/traffic movement, location, humidity, insects, vermin, flooding of the storage area, open/closed shelving the facility should perform a risk assessment to identify all the risks. The risk assessment should include:

- the condition of walls, hard surfaces and shelving units,
- the condition of the storage containers for moisture pooling, dust or dirt
- microbial barrier properties of the packages, if packages are heat-sealed in impervious plastic and the seal is intact or not (qualified packaging protects its contents from adverse environmental conditions, including therein variations of temperature and room humidity).

Temperature and humidity controls are designed to maintain a suitable environment that reduces risk of microbial growth. An intact sterile barrier system should protect the contents from microbial contamination during temperatures and humidity outside acceptable ranges. An isolated one of incident or breach will need to be risk assessed however ongoing and sustained breaches increase the overall risk and potential impact. There is limited evidence that connects breaches of

temperatures or humidity directly to the sterility of contents with an intact sterile barrier system. Inspection and risk assessment is recommended to determine quality status of items within the sterile stock area.

In the event of humidity or temperature concerns in the sterile stock area the HOs should conduct a risk assessment to assure the sterility of the stock (event related sterility principles apply; refer Fig 7):

- Identify all the risks within the sterile stock area/s
- Check walls, hard surfaces and storage containers with lots and/or laminates for moisture pooling
- Check packages for soiling, wetness and moisture.
- Isolate potential contaminated items for further review
- Where no compromise identified and items released for use, HWs should be reminded of responsibilities to check sterility during set up and escalate as required.
- Where the above occurs; additional inspection of sterile stock areas should be conducted
- Where items have been deemed compromised; discard or reprocess.
- Write a brief report with your recommendations on non-conformance of the item and the resultant outcome
- Document and escalate the findings to relevant executive representatives for further decision making

Any issue that compromises sterile stock during transport or storage should have a similar risk assessment and escalation process.