Section 2- Cleaning and Packaging

Cleaning of instruments and equipment

Cleaning is defined as the removal of all adherent visible soil from the surfaces, crevices, joints, and lumens of instruments, and it is normally accomplished using water with detergents or enzymatic products. Meticulous physical cleaning must precede disinfection and sterilization procedures. The *Infection control guidelines for the prevention of transmission of infectious diseases in the healthcare setting* (CDNA, 2006, p16-7) states that “if an item cannot be cleaned it cannot be disinfected or sterilized”.

**Ward areas**

Regardless of the type of cleaning method used, gross soil should first be removed by rinsing with water, a detergent solution or a detergent/disinfectant formulation. Soaking in an enzymatic solution may be required if the exudate has dried. The initial pre-cleaning may be carried out in the area where the equipment was used otherwise it should be cleaned in the central sterilizing department. Direct dispatch to SS should be in closed, leak proof containers.

When carrying out cleaning procedures, protective apparel complying with AS 2161.2 (2005) shall be worn, as stated in AS 4187, the cleaning of instruments in a ward area should be performed in a designated area to prevent possible contamination of clean or processed items. There should be a designated clean area and dirty area for processing instruments, and the area should ideally include the requirements as stated in AS 4187 eg hand washing facilities, good lighting etc.

**Operating rooms**

Cleaning of instruments within the operating theatre should comply with current Australian Federation of Operating Room Nurses (AORN) Standards, Guidelines and Policy Statements. Gross soil is to be removed first prior to the transportation of used instruments to SS in lidded containers or covered trolleys.

**Water quality**

The quality of water is integral to the cleaning process. Routine water testing is often conducted by engineering staff and or engineering contractors, and the utilisation of such a resource would be preferable. Opportunities to share services should be considered in order to prevent duplications and conserve resources. Useful information on the quality of water may be obtained from the local water authority or Population Health Unit and will assist in determining appropriate cleaning agents required for the SS.
Water hardness is determined by the amount of calcium and magnesium ions present in the water. Water hardness reduces the rate of kill of certain disinfectants and generally reduces the efficiency of cleaning chemicals. This occurs because divalent cations (e.g., magnesium and calcium) interact with some chemicals to form insoluble precipitates and a white-grey residue on the instruments.

Possible interactions between very hard water, or water with elevated levels of dissolved chemicals justify the attention required here to the quality of water used for cleaning. These dissolved components of reticulated water have the potential to seriously retard the effectiveness of some cleaning agents and may damage instruments. Also, drying of instruments following a post-cleaning rinse with impure water can produce undesirable precipitated residues of the salts and other elements dissolved in the water.

In some cases where further filtration is required to remove the likes of chlorides, etc, systems such as Reverse Osmosis filtration are employed. This quality of water would normally only be used for final rinse applications.

Water and resource economisation should not take precedent over operational imperatives such as water quality and critical parameters for processes.

**Selection of cleaning agents**

Deposits of dust, soil, and microbial residue on equipment can contribute to healthcare associated infections. Cleaning agents remove organic, inorganic, and microbial contaminants. No single compound has all the properties that are required to remove all fractions of soil deposits. The first step in cleaning is the use of surfactants or surface active agents to reduce surface tension, which assists in soil being held in the cleaning solution.

Chemical suppliers shall provide Product Data Bulletins and Material Safety Data Sheets (MSDS) for all cleaning agents. A guide for selecting cleaning agents can be found in AS 4187.

**Chemical storage**

Chemicals classified as hazardous by Worksafe Australia (as indicated on the Material Safety Data Sheet, or MSDS) should be registered within a facility and stored appropriately. Detergents, disinfectants, and chemicals with high acidity or alkalinity should be stored in a chemical storage cabinet and each MSDS for chemical incompatibilities are to be reviewed before storing different chemicals together.

**Material safety data sheets**

Material Safety Data Sheets (MSDS) provide important information about chemical substances. Suppliers of chemical agents shall provide Product Data Bulletins and the MSDS for all cleaning agents and provide the user with validation that the cleaning agent complies with the recommendations of AS 4187.
Copies of all MSDS should be available to all employees at all times in a designated register so that appropriate action can be taken in case of exposure to a hazardous substance. If information is incorporated into work instructions it is important to use the original wording and refer to the MSDS.

**Chemical spills**

The degree of hazard from a spill depends on the nature of the substance and the amount spilled. All chemical spill management procedures, including spill kits, should be developed in accordance with the MSDS for the particular substance, or other relevant policies. Spill kits should be provided for each cleaning agent that may be hazardous, as well as for blood (refer ‘blood spill cleaning procedure’), asbestos and glutaraldehyde. Contact the facility Workplace Health and Safety Officer for advice.

**Detergents**

A mild alkaline detergent is preferred for manual cleaning, ultrasonic cleaning, or one of the several types of instrument washers. Mild alkaline detergents (pH range 8.0 – 10.8) are more efficient cleaning agents for surgical instruments than neutral pH detergents or surfactant based detergents. It is recommended that facilities work with chemical suppliers to determine the best detergent required as this will be dependent on the facilities water quality.

The term pH refers to a scale which measures acidity or alkalinity:

- pH 0-6.9 = acid
- pH 7.0 = neutral
- pH 7.1-14.0 = alkaline

Information on detergents to be used in ultrasonic cleaners is described in: AS 2773.1, Ultrasonic cleaners for health care facilities, Part 1, Non-portable; and AS 2773.2, Ultrasonic cleaners for health care facilities, Part 2, Benchtop.

To assist in preventing detergent or rinse residue on the instruments the functions of the washer/disinfector and detergent dispenser should be checked daily. Chemical residue has the potential to cause tissue irritation.

**Enzymatic (proteolytic) cleaners**

Gross soil should first be removed by rinsing with detergent and water. If blood or exudates have dried or hardened, soaking in a warm solution of an enzymatic cleaner is required.

Cleaning agents, containing enzymes for breaking down proteinaceous matter, may be used for sensitive equipment if the equipment manufacturer approves their use. Rubber or nitrile gloves are required when handing enzymatic solutions as the enzymatic cleaner will degrade latex gloves.

**Disinfectants**

Disinfectants are not needed during the cleaning of surgical instruments and equipment. Nor are disinfectants required for general environmental cleaning.
Manual cleaning

Manual cleaning can be labour and time intensive but the practice may still be recommended by the manufacturers for the cleaning of items that are delicate or complex. Items that require manual cleaning must be separated from other items when they are received into SS. Prior to cleaning the item is to be checked for completeness. Manufacturer’s instructions must be followed. Manual cleaning is not appropriate for anaesthetic equipment or equipment where thermal disinfection is required.

Staff who undertake manual cleaning should undergo appropriate training and instructions for the dismantling and reassembly of complex instruments should be available for reference.

The manual cleaning process usually involves a system of two, preferably three sinks; one for washing with the aid of a soft bristled brush; the second for the first rinse with tap water; and the third for the final rinse. For the process for manual cleaning including cleaning lumen instruments refer to the Standard Operating Procedures and Workplace Skills Assessments as part of Easi-Sterilise (http://www.chrisqld.com/easi_sterilise/easi-sterilise.html).

Highly caustic agents, abrasive pads and powders must not be used during the manual cleaning process as they have the potential to cause damage to instruments due to abrasions or leave residue on the instruments.

During the manual cleaning process staff must wear appropriate personal protection which includes waterproof apron, rubber gloves (strong enough to prevent punctures or cuts) and eye and face protection. All of these items should be changed when the staff member leaves the cleaning area.

**Brushes and accessories for cleaning**

The criteria for cleaning equipment are per AS 4187. Cleaning accessories should be capable of withstanding thermal disinfection, or they should be single use only. Adequate supplies of disposable non-linting cloths or swabs should be available to allow frequent changing. Cleaning brushes and accessories should be inspected regularly, not used if visibly contaminated and replaced when worn or kinked. At the completion of each day all reusable cleaning accessories should be cleaned and thermally disinfected or sterilized.

Some equipment may be supplied with appropriate cleaning adapters eg endoscopes. Substitute cleaning equipment should not be used unless approved by the manufacturer of the instrument.

**Mechanical cleaning**

Mechanical cleaning using washer/disinfector machines (either batch or multi-chambered design) removes soil from instruments. They offer a number of advantages including: an automated and controlled process, lack of aerosol generation, and reduced staff contact with contaminated instruments.
Washer/disinfectors usually operate within the following temperature ranges:

- **Rinsing**  40°C - 50°C
- **Washing**  50°C - 60°C
- **Disinfecting**  70°C - 95°C
- **Final rinsing**  80°C - 90°C

For thermal disinfection the following times and temperatures must be achieved:

1. 70º for 100 mins
2. 75º for 30 mins
3. 80º for 10 mins
4. 90º for 1 min

Maintenance of mechanical cleaners such as ultrasonic cleaners, batch type washers and multi-chambered washers should follow manufacturer’s instructions as well as the relevant sections in AS 4187.

When procuring new equipment consideration should be given to systems that employ automation for the conveying of items offers advantages by increasing efficiency by maximising machine utilisation also reduces the risk of manual handling injury by reducing the need to double handle instruments or trays.

**Ultrasonic cleaning**

Ultrasonic cleaning is generally used as a supplement to manual or mechanical cleaning or to clean delicate tubes or other hollow instruments such as special syringes or needles. Manual cleaning is to precede ultrasonic cleaning.

Ultrasonic cleaners work by subjecting instruments to high frequency, high energy sound waves that dislodge soil from the surfaces and crevices of the articles placed in the cleaning fluid. A neutral or alkaline, low foaming detergent is suitable; foam is undesirable because it settles on instruments when they are removed from the tank. Rubber and polyvinyl chloride (PVC) cannot be cleaned ultrasonically because these materials absorb the vibrations that are created.

The operation and maintenance of ultrasonic cleaners should comply with the manufacturer’s instructions and with AS 2773. The process for ultrasonic cleaning and specific considerations on the use of ultrasonic cleaners can be found in AS 4187.

**Batch washers**

Mechanical cleaning via specifically designed machines such as batch type washer/disinfectors or multi-chambered washer/disinfectors is available. These machines are used for cleaning instruments and utensils, complex equipment such as anaesthetic breathing circuits, flexible fibre optic endoscopes, and laboratory glassware.

Batch type washers clean baskets of instruments by forced spraying from fixed or rotating arms in a closed chamber; refer to AS 2945 describing Batch-type washer/disinfectors for health care facilities.
Details for washer cycles and specific considerations for batch type washers can be found in AS 4187.

**Continuous Process (multi-chambered) Washer/Disinfectors**

These machines have several stages/chambers with different cleaning, rinsing and drying conditions. They perform a continuous process in which the articles being cleaned proceed on a moving belt/conveyor through a series of chambers on racks or load carriers. AS 3836 provides basic requirements for this type of machine.

The rack conveyor system extends from before the input window of the machine to past the output window to facilitate manual handling of the racks and the items being cleaned.

**Drying of instruments**

Drying reduces the risk of re-contamination during inspection and assembly of instruments, and minimises rusting and staining. Residual moisture interferes with the sterilization process, and can damage instruments. Following any method of cleaning (pre-cleaning, manual, mechanical and ultrasound) instruments need to be dried.

If a mechanical washer (batch or continuous process) has a drying cycle; during validation of the machine it is important to identify what items the process can effectively dry. If there is ever a need to transfer these identified items to a dryer because of residual moisture there is potentially a malfunction in the drying cycle and the machine needs to be serviced and revalidated.

Drying cabinets should be used for drying instruments, hollow ware, tubing and anaesthetic equipment. Drying cabinet operating temperatures shall be within the range 65°C to 75°C. Refer to AS 2514 and AS 2774 for drying cabinets.

Hot air drying may also occur during the last stage of the cycle of washer/disinfector machines, batch washers or multi stage rack conveyor machines. Drying cabinets, and or compliant drying systems must be used for drying of tubing. Alcohol is recommended as a drying agent only for endoscopes, and only if recommend by the manufacturer.
Packaging & wrapping materials and techniques

The purpose of packaging and wrapping of items for sterilization is to provide an effective barrier to maintain sterility following processing prior to use and to permit aseptic removal of the contents from the pack.

Packaging materials

A wide range of packaging materials are available for use in SS. Packaging materials are selected according to size, shape, weight and the intended sterilization process. Packaging material must:

- be compatible with the sterilization process;
- be suitable for closing and sealing;
- free from loose fibres and particles;
- free from toxic ingredients and non-fast dyes;
- be compatible with pack contents under the proposed sterilization conditions

The requirements of a packaging material include:

- permeability to air, steam and gaseous sterilants (i.e. allows removal and penetration to steam) (does not apply to dry heat or ionising radiation);
- resistance to penetration by micro-organisms following sterilization

In relation to microbial penetration, non-porous materials are solid barriers while porous materials are effectively ‘filters’ manufactured to have good control over the probability of penetration by micro-organisms, even at small rates of air flowing through the material, as long as it is kept dry.

Australian Standard 1079 covers several generic types of packaging used in sterilizing services. These and the textile related standards for sterilizing packaging materials are:

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<td>Is a ‘Guide to the selection of packaging materials’ which describes to potential manufacturers of sterilising packaging systems the general conditions and requirements they will need to meet during the intended use.</td>
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Other packaging materials or systems include rigid reusable sterilization container systems, containers for dry heat sterilization, aluminium foil and polyethylene film.
Appropriate processes for different packaging materials

Not all packaging materials or systems are appropriate for all sterilization processes used in health care facilities. AS 4187 describes the different process for which particular packaging materials are appropriate.

Nylon film (sometimes offered for sale in Australia) is inappropriate for use in most in-facility sterilization processes due to problems of air removal and sterilant penetration.

Care needs to be taken in the use of flexible packaging materials in steam Sterilizers. The non-porous web (usually ‘see-through’) is impermeable to steam, air and condensate. Care needs to be taken in the placement of packs made from this material in a Sterilizer; place the pack so that the plastic layer is generally vertical. After sterilization, packs need to be closely inspected for moisture.

If a facility is changing the class of wrapping material eg linen inner and outer paper to an all paper wrapping system; the Sterilizer/s must be revalidated and the drying capacity of the machine checked and adjusted accordingly.

Resistance to punctures and tears

One significant factor in the choice of a particular packaging material for a pack intended for sterilization is the need for the finished sterile pack to resist damage that may occur during handling. Punctures and tears can easily occur to many porous packaging materials, but some are more resistant than others.

Health facility personnel need to monitor the occurrences of damage that do occur and decide on appropriate actions, which may involve the selection of an alternative material.

Papers

Papers including bleached crepe paper and wraps combining cellulose and synthetic fibres are commonly used packaging materials for steam, dry heat and ethylene oxide sterilization. They are permeable to steam, air and chemical vapours and provide an effective barrier if the packs are stored in clean, dry conditions. Medical grade paper is free from loose particles but frees particles if packs are opened by tearing, cutting or by opening a fibre tear seal.

It is important that the paper wraps used within the facility are used inline with the manufacturer’s recommendations, the use of double peel is not recommended as a wrapping method as this increases the probability that the steam may not penetrate the packing material.

Paper is unsuitable for use in the hydrogen peroxide plasma method of sterilization as it absorbs the hydrogen peroxide vapour from the chamber space, thus interfering with subsequent generation of hydrogen peroxide plasma during the cycle.
Reusable rigid container systems

Reusable rigid containers are used for the steam sterilization of large sets of surgical instruments. They are made from metals, aluminium, high-density polymers, or metals and plastic in combination. Perforations in the base and lid are lined with a steam permeable high-efficiency filter material. These containers should be properly loaded in terms of density to avoid problems of moisture retention and increased drying times. After use these containers should be disassembled and cleaned by washing with detergent and water before sterilization. Routine inspection and maintenance of these containers is essential in ensuring their ongoing effectiveness. Container systems are to be validated before use.

Woven fabrics

Woven cotton or cotton/polyester material can be used for heavy packs that are sterilized in pre-vacuum or downward displacement steam sterilizers. They are less resistant as a bacterial barrier than crepe paper but they are more resistant to tearing. Two layers of cloth, or one of cloth and one of paper, with the textile configured as an inner wrap, should always be used. Defects in the fabric, such as holes and threadbare patches, render the wrap ineffective. All textile outer wraps shall be of double thickness. The performance of woven cotton or polyester/cotton materials as microbial barriers is not as good as the many single-use wraps, but in clean, dry storage conditions these wraps should maintain sterility for several weeks.

If woven cotton/polyester materials are used, there should be facilities and procedures in place to inspect and access the quality and suitability of such fabrics for use and reuse.

Very tightly or thick woven materials may impede air removal and steam penetration, and thus should not be used. The exception is the introduction into the Australian market of ‘recyclable barrier fabrics’ made from wholly synthetic materials. These are very durable and thus attractive for use, but validation of the attainment of sterilization conditions and reliable drying should be locally established before they are adopted in a facility.

Non-perforated containers of glass or metal

Glass tubes closed with non-absorbent cotton wool plugs or crimped foil caps may only be used for dry heat sterilization of glass syringes and needles. Because glass is a poor conductor of heat, heat penetration investigations need to be performed. Needles should be supported so that the tip does not contact the wall of the container. Glass bottles, vials and ampoules may be used for the steam sterilization of aqueous liquids by laboratories, and lidded jars may be used for dry heat sterilization of oils. Non-perforated metal containers are only suitable for dry heat sterilization.

Aluminium foil may be used as a wrapping material for large articles, such as surgical drills, which are sterilized by dry heat. Pinholes may occur in the creases and thus a grade of foil thicker than the common ‘domestic’ grade needs to be selected (~75μM). Metals are impervious to steam and gas sterilizing agents.
Wrapping technique

A package should be designed to minimise the risk of contamination during opening and removal of contents. All principle features of a sterile pack such as sealing and layers of packaging material may be compromised by careless opening of the pack.

Individual products may be enclosed in a single layer of wrapping material or they may be double wrapped to reduce the likelihood of contamination when the package is opened. The outer wrap is sealed and provides the bacterial barrier. The inner wrap, which is unsealed, acts as a protective cover during the removal of the article. Wrapping methods are outlined in AS4187.

Sealing, indicators and labelling

- Adhesive tapes, such as ‘sterilization indicator sealing tape’ which are commonly used to fasten wrappings also incorporate a chemical indicator, usually comprising diagonal stripes which darken or change in colour during the sterilization process. Tape adhesive must be stable under the conditions occurring during sterilization and be permeable to the sterilizing agent.
- Heat sealing of flexible packaging materials is the best method for these materials. Seal the laminate to the paper with a continuous adhesive seal of 3-15mm. In the event of breakdown of the heat sealer a seal may be formed by first folding the corners of the open end inwards, then making two or three width-wise folds of the entire open end of the pack followed by securing of the folds with adhesive tape (which could be ‘autoclave’ indicator tape).
- Self sealing packages are to be used in accordance with manufacturers instructions.
- Staples must never be used because they perforate the packaging material
- Labelling of packs should be prior to sterilization using non-toxic, solvent based felt tip marking pens. Labelling should occur on the sterilization indicator sealing tape securing wrapped packs. Pouches should be labelled outside the heat seal line and on the clear (laminate) side as the ink may penetrate the paper. Commercially prepared self-adhering labels may be used, with the advantage that they may be pre-printed and/or computer generated.
- A piggyback batch control label system or computer generated system is to be used on all items that are to be used as a sterile product (refer to CHRISP “Recommendations for manual batch labelling and manual tracking of instruments trays for Operating Suite”), this label is to be placed in the patient’s procedural record by operating suite staff to assist with the ability to recall items. Minimum labelling requirements as described in AS4187 include:
  - Sterilizer identification number or code
  - Date of sterilization
  - Cycle load or number
Specific guidelines for packaging for low temperature processes

The low temperature sterilization processes each have special requirements or limitations for packaging materials. Short descriptions follow:

Ethylene oxide

Many porous packaging materials and sealing styles may be used in ethylene oxide, except for cotton or polyester/cotton textiles which absorb moisture needed for reliably killing microorganisms. Sealed containers must not be used. Different packaging materials (as well as the goods being sterilized) will absorb differing amounts of ethylene oxide during sterilization. Removal of this absorbed gas is a slow process requiring a specific aeration stage and equipment. Packaging materials can have a significant effect on the efficacy of the sterilization process and any change requires that the process be revalidated.

Hydrogen peroxide plasma

Only purely synthetic packaging materials can be used in hydrogen peroxide plasma sterilization. This is because there is no absorbed moisture in the packaging material, very small quantities of which would interfere with the attainment of the deep vacuum and the generation of plasma used in this process. Suitable materials may be selected from the range of non-woven wraps and non-cellulose flexible packaging materials available and are sealed at 120°C.

Peracetic acid

Peracetic acid sterilization utilises a liquid sterilant, therefore porous packaging materials cannot be used because at the end of the process they would be completely saturated with liquid.

This process is intended for sterilization of unwrapped instruments with only a very short distance for transport of goods from the sterilizer to the place where they are used. For this purpose, the load carrying ‘cassette’ offers some protection following sterilization, similar to the way packaging materials function, but these machine specific load-carrying systems are not intended to maintain sterility longer than a few minutes after sterilization.

Heat sealing of packaging material

Heat sealers are used to seal paper to paper (eg bags or pouches), film to paper (eg laminates, flexible packaging systems) and plastics. Heat sealing involves pressing the lacquered surfaces between heated plates. The temperature, pressure and contact times must be constantly monitored. Creases, thickness and type of material used may result in faulty seals. Seals should always be checked on opening to ensure that the seal has been maintained.

Heat sealers shall undergo a complete mechanical service, including temperature calibration, at regular intervals not exceeding 12 months.
Test pieces for each type of packaging material used shall be processed daily on each heat sealer and examined for integrity and strength of seal before and after being subjected to a steam sterilization process.

Various types of heat sealers are available – refer to AS 4187. Heat sealers are either of the jaw-type or of the continuous type. For each type of heat sealer, the operator shall on a daily basis check the following:

- the machine is in a clean condition with no loose fibres or lint present; and
- element covers, where fitted, are in a good condition, and are replaced immediately when damaged

In addition, the operator shall, every three months, check and adjust the gap between the heating elements to ensure that it is within the manufacturer’s recommendations.

The effect of the sterilization process on the seal must be taken into consideration. Heat seals are weakened during steam sterilization but usually return to the normal condition on cooling. Sterilization by ethylene oxide, hydrogen peroxide plasma or radiation does not have a significant effect on seals.

**State purchasing contract – SOA 7**

The Queensland Health Services Purchasing and Logistics Unit administers a whole-of-state ‘Standing Offer Arrangement’ for consumables that are routinely used by sterilizing services. ‘SOA-7’ provides access to tried and tested sterilizing materials and monitoring consumables for use throughout all Queensland Health facilities. SOA-7 includes:

- plastic, paper bags for wrapping/sterilization with or without indicators
- packaging and wrapping systems – flexible, heat sealable and paper
- sterilization monitoring systems – chemical and biological
- sterilization accessories - sealing tape, instrument tips and tray liners.