Section 3 - Sterilization

Definition and Overview

Sterilization involves the complete destruction of all forms of microbial life, including bacteria, viruses, and spores. To be effective, sterilization must be preceded by meticulous cleaning (mechanical or manual) to remove all foreign material from objects prior to undergoing sterilization.

All items introduced into normally sterile tissue, sterile cavities or the bloodstream ('critical' sites) must be sterile. Sterility is also preferred for items used in 'semi-critical' sites (refer to ‘Spaulding’s classification’).

There are a variety of sterilizing methods suitable for health care facilities including steam sterilization (autoclaving), dry heat sterilization, and low temperature sterilizing processes (ethylene oxide, peracetic acid and hydrogen peroxide plasma). The sterilization method chosen must be compatible with the item to be sterilized to avoid damage. Manufacturer’s recommendations are to be followed when determining the method of sterilization for individual items. Single use sterile equipment is an alternative in settings unable to undertake sterilization processes.

Steam sterilization

Steam sterilization involves the use of steam under pressure, delivered at a particular temperature for an appropriate time. Sterilization occurs as the latent heat of condensation is transferred to the load causing it to heat rapidly. Heating denatures any microorganisms remaining following the cleaning process. Wrapped and packaged items must be thoroughly dry prior to removal from the autoclave and procedures must be in place to monitor the sterilization process.

Types of steam Sterilizers

In health care facilities, four generic types of steam Sterilizer may be found:

- the pre-vacuum steam Sterilizer (for porous and cannulated loads) – AS/NZS 1410-2003.
- the downward displacement steam Sterilizer with drying stage (for porous loads) - AS/NZS 2192-2002
- the downward displacement ‘flash’ steam Sterilizer (for unwrapped instruments) - AS/NZS 2192-2002
- the benchtop steam Sterilizer (which is only suitable for porous loads if it has a suitable drying stage) – AS/NZS 2182-1998
Steam quality

Steam quality affects the degree of sterilization and dryness of processed materials. When materials such as dressings, linens, and outer wrappings are sterilized, the fabrics can become saturated with moisture. This in turn hinders diffusion of air from the load and therefore any trapped air can significantly reduce the rate at which a dense porous load will heat.

There are three categories of steam quality that will hinder the efficacy of the sterilization process:

- moisture content of steam (dryness fraction)
- non-condensable gases, e.g.: air content of steam
- particulate or chemical contamination carried in the steam arising from an impure water supply (from which the steam is generated) or improper operation of the boiler or steam generator.

Moisture content

A continuous supply of dry saturated steam is required for reliable steam sterilization. This is steam that is not too wet and not too dry. Excess moisture carried (suspended or entrained) in the steam may cause wet loads, while superheated steam is a problem for reliable sterilization because it is dry and needs to cool before its moisture (necessary for fast killing of microorganisms) becomes available. Steam in the Sterilizer may become superheated during expansion into the chamber from a much higher pressure, or it may be produced through malfunction of some Sterilizer or steam supply components.

The moisture content of the steam (dryness fraction) is measured as the weight of dry steam present in a mixture of dry saturated steam and entrained water. Ideal steam for sterilization is 100% dry saturated steam, although in practice, values greater than 97% are considered acceptable. Inferior moisture content quality can occur due to factors such as boiler priming and poorly trapped steam supply lines. Similarly, superheated steam is to be avoided.

Non-condensable gases

Non-condensable gases are those which do not exhibit a change between gas and liquid states in the normal operating range of temperatures of a steam Sterilizer. They seriously interfere with the heat plus moisture conditions necessary for microbial death.

Air is generally ‘incondensable’ and may be trapped in steam being delivered to a Sterilizer. Other Non-condensable gases may arise from boiler water treatment regimens, or residues of chemicals used to treat the interior of steam supply pipes. Non condensable gas entrainment can be minimised though the correct chemical treatment of boiler water. The removal of non-condensable gases can be facilitated by the installation of air vent assemblies at high points on the steam line before the sterilizer.
Contaminated steam

Steam should not be contaminated by chemical or particulate matter. Chemical contamination may arise from small amounts of ‘carry over’ of chemical laden boiler water during steam generation, while particulate contamination may arise from release of corrosion or precipitated materials in steam supply pipes. It is necessary to remove this contamination in order for reliable sterilization to take place.

The maximum level of contamination given in European Standard EN 285 is 1.0 mg/kg. The qualities of non-condensable gases and physical contamination will largely depend on the quality of the boiler water. In the case of electric benchtop sterilizers, the purer the water supply, the purer the steam will be. This is also true for steam generators and steam boilers, however, steam quality is not solely dependant on the feed water quality, but an overall program including appropriate servicing and maintenance of equipment including a suitable water treatment program where applicable. The only method of removing physical and particulate matter from the steam supply is by filtration.

Steam quality testing

In order to ensure that the end product is as pure as possible, a number of tests can be performed to test steam quality. Results within the specified acceptable levels will show that the quality of steam introduced into the Sterilizer is not harmful to the load.

Steam quality testing is recommended during the commissioning of a Sterilizer and or Steam boiler to establish base line data. Steam quality testing may be considered as part of investigations aimed at pin pointing steam supply issues, but not be considered as definitive proof that a given system will achieve the desired results. Tests have proved that steam systems with a measured dryness fraction of in excess of 98% - delivered to the sterilizers, were still unable to produce suitably dry loads.

Information describing practical methods for testing Sterilizer steam quality can be found in Australian/New Zealand Standard 1410.

Steam sterilization parameters

The fundamental minimum times for reliable sterilization by dry saturated steam at different temperatures usually used for health care facility Sterilizers are set out in AS 4187. The term ‘time at temperature’ is often used. These times commence only after air removal from the Sterilizer chamber and load have been achieved, which means that the time taken for pack centres, and or product internals, to reliably attain the intended sterilizing temperature need to be determined and known. This determination is an essential part of ‘validation’ of the steam sterilization process.

For each working temperature there is a corresponding working steam pressure (when steam is ‘dry saturated steam’), without which, the continuity of the intended temperature could not be guaranteed. Refer AS 4187 to determine temperature for each working pressure.
The time and temperature parameters for steam sterilizing are regarded by microbiological authorities as defining ‘overkill processes’. This is necessary in the typical situation where the number of packs and pack size per load vary.

**Load dryness testing**

The dryness test for pre-vacuum sterilizers, benchtop steam sterilizers and downward displacement steam sterilizers is documented in AS 1410, AS 2182 and AS 2192 respectively under the relevant sections for testing.

The dryness test should have been carried out pre-delivery during evaluation for ‘type’ acceptance, and it should be one of the ‘on site’ tests conducted during commissioning and validation.

The dryness test is essentially the same for benchtop steam sterilizers, and may be carried out by comparing the dryness of a load of sterilized porous articles, after they have returned to ambient temperature following the sterilization process, with the dryness of similar porous articles which have not been sterilized, at the same temperature.

**Fault Finding**

Determination and location of sterilizer failure and faults often requires the cooperation and consultation over many disciplines. It is imperative that when SS recognise a sterilising failure or fault the Sterilizer is placed out of action until Engineering Services has been consulted. Fault finding should follow a logical sequence of investigation and confirmation of factual information and data. A flow chart (Sterilizer Fault Finding- Flowchart) has been provided in Appendix 1 to assist in the formulation of an investigative process.

To facilitate a consistent approach to the technical support for sterilising and maintenance departments a Sterilising Maintenance Network of Advisors has been established with representatives from AMU, District BEMS staff and CHRISP. The Sterilising Maintenance Network of Advisors is a single point of contact for the provision of advice and guidance for Queensland Health facilities experiencing problems with sterilising equipment and steam supply. For further information please refer to the CHRISP website: [http://www.health.qld.gov.au/chrisp/sterilising/sterile_support.asp](http://www.health.qld.gov.au/chrisp/sterilising/sterile_support.asp)

**Wet pack problem in steam sterilization**

Wrapped items need to be dry on removal from a steam sterilizer. Sterilizing and engineering/maintenance personnel can productively work to reduce the occurrences of wet loads and to eliminate problems that have been identified.

Sterilization by steam under pressure works best when steam is of high quality, i.e.: in the range 97% to 100% dryness fraction; steam of this dryness fraction does not deliver excess moisture to the packs being sterilized.
The drying stage of a steam sterilizer, whether a downward displacement or a pre-vacuum type, cannot be relied upon to dry off more moisture than the Sterilizer imparts to packs (by condensation of steam) when it sterilizes them using steam of this quality. For this reason, all items must be suitably dry before being processed by the sterilizer. In either type of sterilizer, the drying stage immediately follows the sterilization stage. During the drying stage, the heat in the load plus the heat that is radiating inwards from the hot chamber walls (heated by steam in the jacket), combine to evaporate residual moisture in all parts of the load. A vapour removal process, usually involving a vacuum in the chamber to lower the boiling temperature thus allows evaporation to continue during the drying stage by removing the water vapour as it is being formed.

There are three areas requiring investigation when persistent wet pack problems occur:

- the quality of the steam supplied to the Sterilizer
- the effectiveness of the Sterilizer (including its various components)
- the methods used by the Sterilizer operators in loading the Sterilizer, including different types of packaging materials.

All three areas may need to be investigated in a particular problem situation refer to Appendix 2 A and B: Troubleshooting of Wet Packs.

Addressing the real cause of wet pack problems

Remedial actions suggested above and in Appendix 2 (A&B) must follow a thorough investigation. The following actions, while common, may not necessarily address the real cause of wet pack problem(s):

- covering loaded lower shelves of sterilizer loading trolleys with a textile sheet or drape to minimise the occurrence of drops of condensate falling onto load items from the shelves above
- extending the drying stage time without carrying out other investigations
- changing the packaging materials in use without carrying out other investigations
- pre-heating the load by leaving it in the sterilizer chamber for a short time prior to the actual commencement of the automatic cycle of the sterilizer. Pre-heating is sometimes successful in minimising the occurrence of wet packs, but it raises a number of unknowns relating to reliable timing and the effect of the preheating period on the long term performance of the sterilizing packaging materials used.

The following points are often erroneously implicated in the occurrence of wet loads:

- superheated steam in the sterilizer chamber (however this is a concern for reliable sterilization)
- the sterilization stage time being longer than necessary for reliable sterilization
- the appearance of wet loads with one packaging material and not others, when in fact the problem is elsewhere in the overall operation of the Sterilizer

For further information, contact Centre Healthcare Related Infection Surveillance and Prevention, Queensland Health.
Flash sterilization

‘Flash’ sterilization is a common term which has arisen to describe the practice of fast sterilization of non-porous and or non-cannulated surgical instruments in an unwrapped condition in downward displacement steam instrument sterilizers located close to point where the instruments will be used immediately. In the past, ‘flash’ sterilization was the predominant way of providing sterile instruments for surgery. ‘Flash’ sterilization delivers the instruments wet and very hot into the operating room environment.

‘Flash’ versus pre-pack

The alternative approach to ‘flash’ sterilization is to provide instruments in a wrapped, dry and cool condition (temperature depending on the time since steam sterilization). This is possible when there is sufficient inventory of instruments and equipment to allow ‘turn around’ time for reprocessing (such as pre-vac sterilizers with fast cycles) in a well-appointed and staffed SS. In smaller surgical facilities, the SS activities often occur in the operating room area; however this represents a compromise of several desirable standards of control of particulate and microbial contamination in the area where sterile packs are being produced.

There is now a strong movement towards routinely preparing sterile instruments in a wrapped, dry and cool condition for use in the operating room. This is because:

- there are immediate advantages to case by case organisation of sterile instruments by operating room personnel
- the typical operating room suite is not designed or equipped to clean instruments as reliably and consistently as a properly appointed SS; there are concerns regarding the adequacy of cleaning and drying of instruments in the operating room prior to ‘flashing’
- sterility of sets of instruments can be uncertain following the use sterilizers designed and intended only for single dropped instruments; they should not be used for routine sterilization of instrument sets
- the sterilizer may not be located in an area immediately adjacent to the operating room; the delivery of flash sterilized devices to their point of use compromises their sterility
- patient injury has occurred from flash sterilized items including: full thickness burns resulting in permanent scars, Pseudomonas aeruginosa meningitis from flash sterilized implantable devices, and surgical site infection.

A compromise is the method of delivery of ‘flash’ sterilized instruments in an enclosed container (with valves that automatically close at the end of steam sterilization) is commercially available (FLASH-PAK™). AS 4187 recommends that the use of such containers are specifically validated. Manufactures recommendations should be observed in relation to minimum time at temperature exposure time. Inspection and maintenance of such systems should be carried out on a regular basis as recommend by the manufacturer.
Monitoring of flash sterilization

Due to time constraints, no reliable biological means of verifying sterilization of instruments or devices can be used. In addition to the use of minimal cycle parameters (ie time, temperature, and pressure) in flash sterilization and the lack of protective packaging, lack of a biological ‘flash-verifier’ further reduces the inherently low margin of safety in ‘flash’ sterilization.

The emergency instrument (‘flash’) Sterilizer should be performance tested daily to ensure the efficacy of the sterilization process (i.e. time at temperature), when:
- biological indicator testing is not performed daily, or
- the Sterilizer does not maintain a permanent record of each cycle

A chemical indicator must be used for each load. Refer to AS 4187.

‘Flash’ sterilization recommendations

- restrict use to emergencies, such as unexpected surgery, or dropped instruments. ‘In most emergency situations, the risk/benefit ratio is low enough that the use of flash sterilized objects is justifiable. In non-emergency situations, however, the risk/benefit ratio is higher, particularly when implantable devices are involved’ (Manian)
- ‘flash’ sterilizers must never be used for implantables, suction tubing or cannulars or any other product not specifically validated for the “flash” process

Minimising ‘flash’ sterilization

The following points should be considered for action to minimise routine ‘flash’ sterilization:
- increase available inventory of particular instruments, particularly rigid endoscopes
- replace older design instruments with newer design, steam sterilizable ones
- provide more instrument sets in wrapped form, focusing on the advantages this provides both during surgery and for management of the operating room suite
- ensure appropriate design of the sterilizing department or sterile processing area to optimise the production and timely delivery of wrapped instrument packs
- organise better shared use of expensive instrument inventory belonging to the District
- manage operating theatre case lists in a way that optimises use of the available instruments in association with their sterile processing requirements
Dry heat sterilization

Dry heat sterilization is only minimally used in health care facilities today. Whereas steam sterilization is fast due to steam delivering both heat and moisture to the items being sterilized, dry heat sterilization subjects items to dry hot air for a long length of time. It is more commonly seen in use in laboratories for sterilization of some glassware items.

Advantages

Advantages of dry heat sterilization include:
- the ability to sterilize goods in sealed or non-porous containers
- the ability to sterilize complex goods while assembled
- the ability to sterilize goods which are impossible to dry in a steam sterilizer or which may be damaged/corroded by the moisture of steam sterilization
- the relative mechanical simplicity of a dry heat sterilizer

Disadvantages

Disadvantages of dry heat sterilization are:
- long times involved in heating, sterilizing and cooling goods being sterilized
- possible damage to packaging materials or to some of the items themselves arising from the high temperatures used
- close monitoring and control of sterilization conditions within packs being sterilized can be very time consuming
- due to the high temperature, dry heat sterilizers provide the greatest potential for injury to personnel following contact with parts of the sterilizer or the goods being processed (while they are hot), compared to the other in-facility sterilization processes
- equipment at the ‘low cost’ end of the market does not adequately maintain constant temperature conditions within the sterilizer. Purchasers may not be adequately aware.

Sterilization parameters for dry heat

Dry heat sterilization parameters are simply time and temperature. After attaining the sterilization temperature, the temperature must be maintained for a minimum length of time. This ‘time at temperature’ must be demonstrated to occur in the case of every pack placed in the sterilizer.

While even higher temperatures (for shorter times) may be used, in health care facilities it is usual to only use the time at temperature combination of 160ºC for 120 minutes (plus penetration time). Penetration of heat into packs prior to commencement of this minimum time at temperature must have been assured.
Monitoring of dry heat sterilization

- temperature measurement using thermocouples is the best method of assessing the attainment of time at temperature conditions and validation of the process
- biological indicators may be used, but containing a different type of micro-organism to those used to monitor steam sterilization (refer AS 4187)
- chemical indicators used in dry heat sterilization are useful only for determining the ‘sterilized’ or the ‘not yet sterilized’ status of goods to which they are attached

Low temperature sterilization processes

The increasing use of rigid and flexible endoscopic instruments which may be damaged when exposed to the temperatures achieved in steam and dry heat sterilization (121ºC and 160ºC) has driven the development of alternative reprocessing methods for heat-sensitive equipment. While steam sterilizable rigid endoscopic instruments have been developed, the need to reliably sterilize many other types of heat sensitive instruments still remains.

There are three low temperature sterilization processes identified by AS4187 for use in health care facilities to sterilize items at temperatures of 55ºC or lower. The active sterilants of these processes are ethylene oxide, hydrogen peroxide plasma, and peracetic acid. All liquid sterilants shall be registered with the TGA.

The immediate advantage of the low temperature processes is that heat-sensitive items can be sterilized within health care facilities. However, because of the significantly higher costs of operating low temperature sterilization processes, items for sterilization should be steam sterilized where possible.

Ethylene Oxide (EO)

After an air removal stage using a vacuum, sterilization is achieved by ethylene oxide gas in controlled conditions of humidity, temperature, time and gas concentration. Gas is supplied in canisters that are used one per cycle. Aeration of all load items is required after sterilization. Risk of personnel exposure to ethylene oxide demands environmental control equipment be in place. There is a very limited availability for this type of processing within Queensland and consideration must be given to procuring instruments or items that can undergo other processing methods other than EO.

Hydrogen peroxide plasma

After air removal by a very deep vacuum and plasma stage, sterilization is achieved through generation of a plasma of hydrogen peroxide vapour within the load by radio frequency excitation. The sterilizer monitors and controls the rate of attainment and depth of the vacuum drawn, energy required to initiate plasma within the chamber, and duration of each stage. (‘Plasma’ is matter excited to a higher energy state than its gaseous form).

At the end of the cycle hydrogen peroxide vapour is replaced by filtered air, and the hydrogen peroxide vapour is converted back into water and oxygen. Automated machines using hydrogen peroxide plasma to chemically process medical and surgical instruments are currently available. This method is normally used for wrapped items.
Peracetic acid

Peracetic acid, or peroxyacetic acid, in low concentrations is characterised by a very rapid action against all microorganisms including bacterial spores. Peracetic acid remains effective in the presence of organic matter and is sporicidal even at low temperatures.

Little is known about the mechanism of action of peracetic acid, but it is believed to function in a similar manner to other oxidising agents. It denatures proteins, disrupts the cell wall permeability, and oxidises sulph-hydryl and sulphur bonds in proteins, enzymes, and other metabolites.

Sterilization is achieved by contact of every part and surface of each item with a 0.2% solution of peracetic acid. The sterilizer creates a fresh sterilant solution from water combined with a powdered concentrate supplied in a single usage container. During the cycle, temperature (50°C-56°C), concentration of peracetic acid and time of exposure (12 minutes) are controlled, and sterilant is circulated throughout instruments being sterilized. A chemical neutralising agent is used in the final stage of the process to return items to a useable condition. Several different load carrying trays or containers are available to accept a variety of instruments being processed.

Automated machines using peracetic acid to chemically process medical and surgical instruments such as endoscopes and arthroscopes are available. Manufacturer’s data demonstrate that this system inactivates Bacillus subtilis and Clostridium sporogenes when the solution is heated to 50°C with an exposure time of 12 minutes or less. These systems have been registered by the Australian Therapeutic Goods Administration as a sterilization process when used according to its manufacturer’s recommendations. They are ‘point of use’ Sterilizers for unwrapped items as recommended by the manufacturer only.

Loading and unloading of sterilizers

The principles governing loading and unloading of sterilizers vary according to the type of sterilizer. In most cases involving wrapped sterilization, a significant difficulty for reliable sterilization exists when packs are loaded into the sterilizer such that they are pressed together.

Instead of the load being several smaller packs, the sterilizer ‘sees’ such a load as one large pack, requiring a longer sterilant penetration time than is needed for each of the packs by itself. The total sterilizing stage time may not be long enough to reliably sterilize this dense load and, for steam sterilization, drying of the load after sterilization may be ineffective.

Final assessment of reliable sterilization is determined when the sterilization process is being validated (refer AS 4187). Information related to loading and unloading of sterilizers is presented in AS 4187. Specific considerations for the different sterilizing processes follow.
Loading and unloading in steam sterilization

- heavy instrument sets (which generate large quantities of liquid condensate) should be placed on lower shelves if the condensate cannot be diverted away from lower items. This may avoid wetting of other packs
- items need to be placed in such a way that air and steam can move between and past them. Light contact is possible and likely but it should not affect sterilization
- non-perforated trays, hollowware and other containers must be placed in such a way that liquid or air (heavier than steam) is not likely to be retained e.g. tilted on the edge to facilitate air removal, entry of steam and removal of condensate
- flexible packaging material should be loaded on edge paper to laminate or flat with the paper facing downwards
- when unloading sterile instruments from a ‘flash’ steam sterilizer and when they are about to be used sterile, locally valid policy should be developed to ensure a low probability of recontamination of the instruments as they are transferred to the sterile field

Loading and unloading in dry heat sterilization

- packs or other items being sterilized need simply to be placed on the perforated shelves of the sterilizer without contact between each other

Loading and unloading in ethylene oxide gas sterilization

- items need to be placed in such a way that air and ethylene oxide can move between and past them. Light contact is possible and likely but it should not affect sterilization

Loading and unloading in hydrogen peroxide plasma sterilization

- items need to be placed in such a way that gaseous movement can occur between and around the items, refer to manufacturers recommendations. Light contact should not affect sterilization

Loading and unloading in peracetic acid sterilization

- the Sterilizer manufacturer’s load carrying trays (specifically designed for particular types of instruments) must be used in order to achieve thorough sterilant contact with all instrument surfaces
- when unloading instruments from a peracetic acid sterilizer and when they are about to be used sterile, local policies should be developed to ensure a low probability of recontamination of the instruments as they are transferred to the sterile field
Cooling practices following sterilization

For items wrapped in porous packaging materials, the period of time between their removal from a Sterilizer (any type) and their return to room temperature is the most critical time with respect to assurance of sterility. Cooling generates a tiny flow of room air into the pack at flow rates demonstrated to breach porous packaging materials leading to their failure to provide a microbiological barrier.

Correct cooling practice is essential to maintain sterility. When a sterile item is not cooled in the correct manner the article can have moisture build up, which can contaminate stock. The item should be discharged if the packaging is torn, punctured or wet.

Before any sterilized items is used it is necessary that the item be in the temperature range of 18-22°C with relative humidity of 35-70%. In general this can be achieved with a cooling time of two hours however it does depend on the density of the item processed.

AS 4187 recommends that at the end of the sterilization process, stock should be removed and inspected for signs of moisture. Sterile packs removed from a steam sterilizer should be cooled on a mesh surface to prevent the packaging from sweating.

Do not place items on a solid surface or use forced cooling methods including fans or boosted air conditioning. If a plastic dust cover is to be applied, it needs to be applied after the sterile item has completely cooled.

The equipment storage area must be free from dust, draughts, dampness and high traffic activity to minimise bioburden and environmental contamination. All sterile packages should be handled as little as possible to decrease risk of contamination.

Rejection of items intended to be sterile

AS 4187 lists conditions under which a product is considered non-sterile. These may be summarised as items that:

- are incorrectly wrapped
- are damaged or opened
- are still wet after the sterilizing cycle or comes into contact with a wet surface
- have been placed or dropped on a dirty surface
- have no indication of having been through a sterilizing process
Storage of sterile stock

Immediately following sterilization, items should be minimally handled and stored in a low traffic area while cooling (refer AS 4187). Objectives related to sterile storage are:

- to manage sterile stock maintaining the requirements of AS 4187
- to provide end users with a product that has been reliably sterilized, and maintained in a sterile state
- to apply sound techniques of inventory management and infection control

Storage conditions

Ideally, sterile storage areas should be air-conditioned with minimal air turbulence created by fans. The following points are minimum requirements whether or not storage conditions are air-conditioned:

- area to be dedicated for sterile stock storage
- free from dust, insects and vermin
- temperature range to be between 18°C to 22°C with a relative humidity ranging from 35% to 68%
- possible deterioration of materials and/or components of sterile articles must also be considered. Manufacturer’s instructions as to the likely life of an item’s components (eg latex, or maximum recommended number of wash cycles) need to be considered

Shelving, containers and handling

- consideration should be given to wire rack compactor systems as these increase efficiency and storage space
- shelving systems are to be designed and constructed to avoid inaccessible corners, with sealed seams, having non-porous surfaces which facilitate damp dusting and vacuum cleaning
- shelving to be 250 mm above the floor and 440 mm from the ceiling
- area to be protected from direct sunlight
- sterile items are to be stored within the original packaging or decanted into receptacles which are enclosed and able to be cleaned to reduce risk of contamination and/or damage
- reusable cardboard boxes should not be used as storage containers as they are porous and cannot be adequately cleaned and may harbour organisms
- a system of inventory review and stock rotation based on the date of sterilization must be developed
- routine cleaning with detergent and water to be scheduled and procedures to be documented
Transporting sterile stock

In order that protection of sterile stock is ‘seamless’, the same factors which may compromise storage of sterile stock need to be addressed when it is being transported.

The following are important:
- avoid moisture and condensation
- avoid incorrect temperature
- avoid excessive exposure to sunlight and other sources of ultraviolet light
- avoid exposure to vermin and insects
- containers used during transportation need to be such that sterile stock does not experience extremes of storage or handling. Assessment and planning is required in order to determine the most appropriate container for the particular situation. Strong, easily cleaned, plastic containers with clip on lids are often necessary, depending on the distance transported and the training of the personnel who may be involved in transport of containers of sterile stock
- transport vehicles must have a dedicated space for containers of sterile stock

Access to sterile stock storage area

- access to the area shall be clearly defined
- traffic should be controlled to minimise the movement of airborne contaminants
- adequate education and training must be given to all staff in handling sterilized articles

Shelf life and event related sterility

The use of time-related expiration dates for the determination of shelf life for sterile items has been widely recognised as meaningless (Gardner & Peel, 1998). For many years a sterile storage time of four weeks has been the tradition, followed by recall, repacking and reprocessing of all facility manufactured stock not used within four weeks of sterilization.

The alternative is a system called ‘event related sterility’ which declares that the sterility of an item depends on the events occurring during storage of that item. Possible and probable events compromising sterility vary from one facility to another; therefore sterility maintenance must be viewed as a quality management exercise in each facility, comprising monitoring, evaluation, planning and instigation of changes as necessary.

Events that could compromise package sterility may arise from:
- the type(s) of packaging materials or packaging system in use
- package design
- the after effects of any failure(s) during cleaning and/or sterilization of the item(s)
- conditions occurring during storage and handling eg packaging damage, soiling, becoming wet, exposure to vermin, etc.
- materials deterioration of the product or its component parts
As part of the quality management process, any or all of these factors may be altered to improve the likelihood of maintenance of sterility for long lengths of time. Another factor important in establishing an ‘event related sterility regime’ is education of all personnel involved in handling sterile stock, including users (medical and nursing personnel).

In practice, the introduction of an event related sterility regime is a major exercise involving detailed assessment of all areas in which sterile stock is stored. There is a need to both influence and control the conditions of storage and all handling ‘experiences’ endured by stock during storage.

Broad steps towards the introduction of an event related sterility program are:

- evaluate the present situation in every user area where sterile stock is stored
- plan stages and timing of implementation, including on-going monitoring of sterile storage conditions and problem reporting mechanisms will be implemented
- raise awareness of the concept of event related sterility amongst all sterile stock users and the need for their involvement, and local plans for its introduction
- educate users as to their responsibilities for assessment of sterile packaging integrity every time they open a packaged sterile item (both in-hospital and commercially made), particularly in relation to providing feedback to the SS
- pilot the introduction in one user area for six months, utilising the date of sterilization as a reference for the length of time packs have remained on shelves
- determine the potential for adjustment and management of numbers of packs needing to be stored in each user area
- evaluate potential for more widespread introduction throughout the facility, involving assessment of observed condition of all packs
- modify (if necessary) plans for full introduction
- introduce event related sterility programme facility wide
- monitor and evaluate on a regular basis, documenting all data, observations and user reports to facilitate later quality improvements
- implement improvements as necessary on a continual basis

It should be noted that it is not possible to clearly interpret results of attempts by hospital laboratories to evaluate microbiological contamination in packs that have been sterilized, to either support or not support the introduction of an event related sterility program. Such assessment is of less importance to the program’s introduction than careful monitoring and evaluation of the events that sterile packs experience during storage.

Where an ‘event related sterility’ regime has not been properly instituted, observance of the ‘traditional’ four week shelf life with repacking and resterilization each time is the only alternative.