

# **INFECTION CONTROL**

## **FOR**

# **GENERAL PRACTICE**

### **Practice Visit notes**

1. Handwashing and skin disinfection
2. Surface Cleaning and Disinfection
3. Instrument Processing and Validation
4. Clinical Waste Management
5. Sharps/splash injury and risk of infection
6. Staff immunisation

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# **1. Handwashing and skin disinfection**

## **Transient, transitional and resident skin bacteria**

Skin flora is the range of microorganisms normally found on the skin and is a combination of resident, transitional and transient microorganisms. Resident bacteria multiply within the outer layers of the skin and around sweat glands and are not removed by soap but are temporarily suppressed by skin disinfectants.

## **Correct handwashing technique**

1. Wet the hands before applying any product in order to reduce skin damage. The volume required will be displayed on the bottle (generally 1-2 mls).
2. Washing involves rubbing hands together with the product for at least 15 seconds. To clean webs of fingers, place fingers from one hand over the webs of the other in a clenching action and rub. Avoid scrubbing with a brush because it may damage skin.
3. Rinse hands well under running water (prevents product remaining/skin damage).
4. Dry hands with a patting action, not a wiping action. Use paper towel or clean cloth towel. Residual moisture on hands transmits more bacteria than when hands are dry.

## **When is a skin disinfectant required for handwashing?**

Combined with gloves it will provide an effective barrier and is necessary for contact with non intact tissue and mucous membranes. Three minutes contact for surgery is recommended while 30 seconds may be adequate for wound dressing. If soap is used for sterile work instead of disinfectants, hands become moist under gloves and bacteria pool and migrate through any holes to vulnerable tissue. Skin disinfection prior to glove use reduces the numbers which may be transferred. Prior to surgery, use a 4% concentration of chlorhexidine gluconate in a detergent base.

## **Use of alcohol based handrubs and correct technique.**

Alcohol based handrubs are used for skin disinfection where sinks are not conveniently located. Hands are washed once a sink is accessed.

## **Gloves**

Sterile gloves are used for sterile procedures in combination with skin disinfection to provide an effective barrier to protect the patient's sterile tissue. Defects in gloves are well documented. Skin disinfection with use of non sterile gloves is adequate for contact with non intact mucous membranes or when performing wound dressings. Gloves are removed after use to reduce skin damage and remove powder. Washing after glove use reduces bacterial numbers which have accumulated in the moisture.

## **Handcream**

This will assist reduce skin damage from washing and alcohol but do not overuse at work or it may impact on the effectiveness of hand hygiene. Use at main breaks.

## **Jewellery**

Jewellery except for plain bands should not be worn on duty because it may cause damage to patient skin, tear gloves or catch. All rings are removed for surgery.

## **Nails**

Keep nails short and do not wear artificial/extended nails. Ensure nail polish is not chipped - rough surfaces protect bacteria and prevent effective cleaning.

## **2. Surface Cleaning and Disinfection.**

### **What is cleaning and disinfection?**

Cleaning is the removal of foreign matter and is achieved with detergent diluted in warm water and applied with a clean cloth/paper towel and correct technique. A good technique and detergent can reduce numbers by 90%. Disinfection kills pathogenic (infection causing) microorganisms but disinfection without first cleaning is ineffective.

### **Correct cleaning technique**

Reduce inhalation of sprays by applying diluted detergent close to paper towel. Fold towel after each detergent application to prevent redistributing bacteria. Wash and dry microfibre or reusable cloths after use. Avoid abrasives - scratches trap bacteria.

### **Toys**

Provide only washable toys and remove after obvious mouthing. A daily wash in detergent and warm water is hygienic and will interrupt transmission of infection.

### **Carpet, curtains etc**

Carpet should be steam cleaned regularly. Upholstery, non removable fabrics and curtains may be professionally cleaned as needed. Spot clean with shampoo.

### **Linen.**

Machines labelled for domestic use may not satisfy standards for public linen. Linen requires adequate changing to avoid accumulation of body odour. Decide if linen is necessary – plastic pillow covers can replace pillow cases. Check modesty blankets for odour/stains and launder regularly. Use plastic backed sheets where fluids are anticipated. If a spill occurs, change linen and clean couch with detergent and paper towel. Ask your laundry for a pre-treatment procedure for bloodied items and leak proof bags eg rinse/Napisan bloodied items before placing in bag. If linen must be washed at home, presoak any spillages at the practice first in Napisan.

### **Cleaning of small blood spills on surfaces associated with patient treatment.**

If linen is not used, clean treatment couch between patients with detergent and paper towel to reduce body odour. If a small blood spill has occurred, absorb this with damp tissue then clean site with detergent and paper towel. Use a disinfectant if necessary. Viraclean is appropriate but 10 minutes contact is required.

### **To Disinfect or not**

Cleaning is usually sufficient and reduces the number of infectious particles so they are insufficient to transmit infection. However, disinfection may be considered if

- the spill occurred on a porous surface eg tiled areas with grout
- the spill surface is in contact with bare skin eg treatment couch.
- the nature of the potential pathogen and the amount of it may pose

### **Decontamination of vomit spills.**

Cordon off the area with a table/chair. Apply absorbent material such as kitty/mouse litter to create a solid and reduce odour. Wearing gloves, mask & apron, remove solid with cardboard scoop and place in bag then in clinical waste. Clean the spill area with detergent by patting not wiping until as dry as possible. Do not disinfect carpet or non removable covers. Consider steam cleaning if the patient has known gastroenteritis.

### **3. Instrument Processing and Validation**

#### **Cleaning, Sterilisation and Validation of instrument processing**

Practices need to annually review documented protocols for the total process with

1. Written procedures for all stages of the process.
2. Evidence of staff training
3. Steriliser maintenance and service records
4. A record of monitoring for every cycle.
5. Results of annual validation of the steriliser cycle.

#### **I. – Cleaning of the instrument reprocessing environment.**

##### **Hygiene**

The instrument processing area is ideally a dedicated room but it is frequently located in the treatment room and occasionally in a consulting room which is not ideal.

The basic hygiene requirement is that instrument processing not be near food areas because a separately located sink is required just as there is a separate sink for washing hands after using the toilet. Splash and transfer of significant numbers of microorganisms occurs when washing instruments.

##### **Surfaces.**

Detergents (always diluted) are used to clean surfaces such as benches, sinks, taps, plastic washing bowls and containers and the external area of the steriliser. The detergent used for instrument cleaning is generally also suitable for bench cleaning: make up a small volume (eg 200 ml) daily in a pour bottle. If using a spray bottle, apply detergent close to paper towel to avoid aerosol generation and wipe surface ie do not spray otherwise inhalation of aerosols or droplets which contain detergent and/or detergent and microorganisms may occur. Wipe the surface clean then dry with fresh paper towel. Rinse the bottle out each evening and drain to dry overnight.

Rinse and wipe dry with paper towel all containers, washing bowls and sinks after each use. Use gently running water to avoid splash. Taps should be wiped clean after use and if the sink is shared with handwashing, a small glad bag placed over the tap during cleaning reduces tap contamination.

Disinfectants may be used after cleaning where a visible blood spill has occurred where there is a risk of blood/body fluid entering sterile tissue eg. treatment couch.

Detergents are considered sufficient if a small blood spill has occurred.

##### **Cleaning of aprons, gloves, safety glasses.**

Change uniforms and gowns after a spill. For hygiene, change uniforms daily. Gowns worn over clothes are not worn outside the treatment area but should be changed regularly eg. daily. Wash external surface of utility gloves with detergent while they are being worn then dry with paper towel. Wipe plastic apron with paper towel and detergent and hang to dry. Remove safety glasses, apply detergent then rinse under running water and dry with paper towel. Store glasses separately from gloves to avoid cross contamination.

## **CLEANING & STERILISATION OF INSTRUMENTS**

1. Wearing protective gear, open all contaminated surfaces and remove visible soil from the instrument by rinsing with warm water or wiping with paper towel, then place item in a labeled container of dilute detergent if cleaning is not to occur immediately.
2. Perform cleaning by immersing instrument in a sink or bowl of warm water with detergent. Brush all surfaces clean under the water.
3. Rinse instrument in warm to hot gently running water.
4. Dry instrument with lint free towel and check for cleanliness.
5. Place instrument in pouch and seal correctly.
6. Label pouch for date and batch.
7. Load pouches in the upright position using a rack for separation.
8. Place rack on a tray so that pouches do not touch chamber walls or each other.
9. Check cycle monitor is present (Printer or Class 4, 5 or 6 indicator)
10. Ensure water level is adequate, close door and switch steriliser on, using only the cycle for which it has been validated.
11. After completion of the drying cycle, open the door, remove tray and place on cake rack to allow load to cool.
12. When cool check to see that all packs are dry and that the cycle has passed.
13. Record the results of each cycle after completion.
14. Place instruments in a dry, covered area for storage.

### **If sterilising off site insert after 4**

1. Transport washed/dried items in a sealed labelled "dirty" container.
2. Receive sterilised items in a sealed labeled "clean" container.
3. Ensure that on arrival, pouches are dry with no tears, that the pouch indicator has changed colour and that they are labelled for date and batch -record this.
4. If your off site facility is not accredited then seek records of cycle results.
5. Keep a record book of incoming pouches and place patient name against each.

## **II. Precleaning or initial treatment of used items**

Initial treatment of the used item takes place immediately after use and involves removal of visible soil. All surfaces are opened and rinsed with warm water or wiped with a dry or damp paper towel or tissue to prevent adherence of organic matter. Wear apron, safety glasses and utility gloves if rinsing or just gloves if wiping.

Avoid hot or cold water on dirty instruments – hot water causes organic matter to stick due to coagulation of protein - cold will cause solidification of body fats.

If there is a delay in performing initial treatment, matter dries onto the item and is difficult to remove even with brushing. Such an instrument may not be sterilised because microorganisms contained within the matter may not receive sufficient contact with heat and steam for sterilisation to occur. (If it's not clean, it's not sterile)

The person who generates the dirty instrument is responsible for ensuring this occurs immediately either by performing it him/herself or by asking another trained person to perform it immediately after use. It is not good practice and it is not safe to place a visibly soiled item directly into a container of detergent because accumulation of contaminating material occurs. However, sometimes this is the only practical option and is better than leaving a used item to dry out but it does pose a risk to staff.

Most practices do not have the resources to follow initial treatment immediately by cleaning after use of every instrument. The standards are silent on what to do if there is a time delay between these two steps but an option is to place the wiped/rinsed item in detergent in a labelled sealable plastic "holding" container until there is time later to complete the cleaning. The main purpose of placing items in detergent is to prevent inadvertent use, rusting and to facilitate cleaning. For surfactant detergents, no minimum or maximum time is noted, but reduce bacterial growth by precleaning before placing in detergent and washing frequently so that items are not left in detergent for too long ie at least daily and twice daily if possible. If the practitioner prefers to use a container for instruments which are generated in his/her room, then discuss wiping of items to satisfy the standard and avoid rinsing instruments in the consulting room handwashing sink for reasons of hygiene and safety. Transferring contaminated solutions across corridors is a safety issue too and the best option is for the user to bring wiped items in a dish to the central processing area for placing in detergent.

Almost all office based practices perform manual cleaning (ie no washer disinfectors used). The preferred detergent is a slightly alkaline, free rinsing, non sudsing surfactant detergent –Clinidet (slightly alkaline) is more in line with the standard but Sonidet (neutral) is acceptable for accreditation. For washer disinfectors, a two stage wash with alkaline then enzyme detergents is proposed. Detergent loosens soil and bacteria but is not a disinfect - it can negatively affect the bacterial membrane.

There are differing views on use of enzyme detergents with respect to safety but they are superior cleaning agents when items are grossly soiled or have been left to dry. They are the detergent of choice for endoscopes.

Clean the sink with detergent and paper towel after instrument processing and then dry it with paper towel to prevent accumulation of microorganisms.

### **III. Cleaning by manual or ultrasonic methods and drying**

#### **Manual**

Manual cleaning means brushing all surfaces in warm water and detergent. Use utility gloves, plastic apron and safety glasses/face shield - not prescription glasses.

If instruments have been placed temporarily in a “holding” container, gently tip off the detergent to avoid splash. Now rinse the sink with dilute detergent and dry with paper towel. Fill either the sink or washing bowl (if you have only one sink) with warm water and detergent to the required volume. A rinsing sink is used on the opposite side to the dirty holding container. Use sterilisable brushes and a disposable cytobrush. Do not use abrasive cleaning agents because scratches trap matter/microorganisms

Take each instrument individually through the process by removing it from the drained “holding” container (or directly from initial treatment if you are proceeding straight to cleaning), open it and brush all surfaces in the “dirty” sink or washing bowl under the water to avoid splash. Then rinse under warm/hot running water in a “clean” sink and place on a clean plastic backed surface eg a bluey with a piece of lint free towel on it. Workflow is from dirty to clean to avoid recontamination.

It is preferable that handwashing be kept separate from instrument processing. If you have two sinks and the processing is occurring in the treatment room, label one sink for handwashing so that it is dedicated for that purpose and use a washing bowl and the other sink for instrument processing. An alternative is to share the “clean” rinsing sink with handwashing. Remember to clean taps after instrument processing.

#### **Ultrasonic Cleaning**

Ultrasonic cleaning is superior to manual cleaning especially for serrated surfaces because it can dislodge matter from these hard to reach surfaces. As a comparison, ultrasonic cleaning removes 99% of soil compared with 92% for brushing. It functions by generation of tiny vacuum bubbles which crash against instruments and shatter or dislodge any matter. The detergent used will aid cleaning at the point of contact.

Test daily to check that the frequency of the ultrasonic waves is high enough and spread evenly through the tank. To perform: Hold a piece of alfoil on its edge (like toast in a toaster) and place in the tank without touching the bottom. Use water without detergent for this test. Turn the machine on using a 10 second degassing cycle then remove foil to check for even pitting. Rinse tank to remove aluminium and fill with detergent and water and degas ready for use. Change the solution daily and more often if solution appears visibly contaminated – this reduces material deposited on instrument. Rinse items under running warm water to remove adherent matter.

#### **Drying**

A disposable or reusable lint free towel is used because fibres may cause reactions in sterile tissue - see Appendix 2 for products and contact details. Low lint towels are often used but avoid paper towel. A reusable non linting towel requires washing after each use. Prevent latex and powder entering sterile tissue by using reusable vinyl utility gloves when drying washed instruments. Gloves protect both user and clean instrument from contamination. Avoid touching instruments with the bare hand - body oil adheres and steam cannot penetrate this. Do not air dry instruments because contamination may occur. Pat instrument dry to remove moisture.

## **IV. Processing of non critical and semi-critical items.**

### **Categories of procedures/instruments**

The Spaulding classification divides procedures into non critical, semi critical and critical. Non critical do not involve contact with mucous membranes or non intact skin. Semi critical procedures are in contact, even indirectly, with mucous membranes and sterilisation is required. Items in contact with sterile tissue must be wrapped.

### **Labelling of instruments**

If an item is labelled for single patient use then it should not be used for other patients. If an item is labelled disposable then it should not be reused.

### **Plastic ear pieces for otoscopes**

Many brands are disposable so check first. If they are reusable, brush them in detergent and rinse them. After drying them, place in a covered container. The external surface may be wiped with an alcohol swab for 15 seconds.

### **Ear syringes**

Ear syringing is a non critical procedure for intact ear canals. After use, disassemble and clean – use a cytobrush for the ear piece. Dry and regrease. If the syringe is continuous flow then drying is problematic. If syringing must be performed on non intact ear canals use a sterilised ear syringe. An alternative is to use a 50 ml disposable syringe. Be aware that attachments have been ejected into the ear.

### **Spacers**

These are categorised as semi critical. If labelled single patient use, observe. If the spacer is labelled for multi patient use then it is disassembled, washed and steam sterilised. Refer to instructions regarding coating fresh detergent to reduce static electricity prior to use. Keep new spacers (as per guide) and/or purchase those labelled multi patient use and which are able to be sterilised according to directions.

### **Nebulisers**

They are usually single patient use but if not then follow directions for cleaning and ensure that any part that is deemed semi critical is either disposable or sterilisable.

### **Other respiratory devices eg for spirometry**

The same classification applies (NHMRC guide for specific references). Do not clean inside of tubing (replace if necessary). Consider direction of airflow and presence of filters if no information is available. Use single use spirometry mouthpieces.

### **Vacutainer barrels**

The manufacturer indicates these are not for critical use and simply need to be clean before use. Wash in detergent. The yellow type may be steam sterilised.

### **Diathermy, cautery and cryotherapy equipment**

Use single use cryotherapy and electrotherapy tips where the procedure is semi critical. Avoid any product where sterilisation is indicated by chemicals (hazardous)

### **Brushes**

Wash and sterilise in the last load of the day. If there is no steriliser, wash with hot water, rinse and dry. Use disposable cytobrushes for accessing hard to reach areas.

## **V. Packaging, sealing and labelling of instrument packs.**

### **Packaging**

An item in contact with sterile tissue is for critical use and must be sterile at point of use. ie. it is wrapped prior to sterilisation or is sterilised unwrapped then immediately used (not recommended). If an item is for use on intact mucosa eg a speculum for a pap smear, then it is for semi critical use and is sterilised between patients but is not required to be wrapped. If it is used in the insertion of an IUD, then this for critical use and a speculum is required to be sterile at point of use ie wrapped. Many practices wrap all specula for aesthetics, also to avoid mix ups and reduce contamination.

Packaging may be laminated pouches, paper bags, continuous roll, double thickness sheets eg kimguard and must be of standard quality. Pouches have a heat sensitive Class 1 process indicator often in the shape of an arrow impregnated onto their surface. This changes colour on exposure to heat, as does steriliser tape. This is not a control but identifies processed loads. For kimguard and continuous roll packaging, heat sensitive tape impregnated with chemical indicator is used for sealing.

It may be easier to place each item in a pouch as drying is performed – this saves double handling but if there is a delay then place dried items in a labelled clean, sealable container until sufficient pouches are available to make up a load. Do not leave unsterilised pouches within view as they may be used inadvertently.

If items are not to be sterilised straight after the cleaning process, store unwrapped in a well labelled container to avoid inadvertent use.

### **Pack contents**

In a pouch there may be sufficient room for 4 or 5 instruments. Steam must be able to reach all surfaces – this and drying are facilitated by correct loading. Prepare various combinations of instruments and sufficient single items. Avoid dense material and if processing gauze, use only 4 or 5 pieces per pouch to assist drying.

### **Sealing**

When using self seal pouches, seal along perforated line so that surfaces align. It will be easier to leave the sealing until all items have been placed in pouches. Wash and dry hands after removing gloves - wet hands transmit bacteria through pouches. If using roll pouching, double fold edges and ensure tape extends 2.5 cm to paper side.

### **Labelling**

Label for date (including year) just prior to sterilisation (not in advance) and cycle or load number (use the cycle number generated by the printer). Use a laundry marker or peel off sticker to enable transfer of information when tracking critical instruments.

### **Hollow ware**

If a bowl or dish requires wrapping, place the hollow side against the paper rather than the plastic side – this facilitates drying.

## **VI. Transport of instruments for off site processing/documentation.**

### **Transport of instruments for off site processing**

- 1 Transport washed and dried items in a sealed labeled “dirty” container.
2. Receive sterilised items from the off site facility in a sealed labeled “clean” container.
3. On arrival, check the condition and labeling of pouches and any results sent.
4. A record of incoming pouches is kept to place the patient’s name against each in the event of a recall.

### **Advised Requirements**

1. There are separate containers for unprocessed and processed items.
2. Provide the off site processing facility with a copy of your cleaning protocol.
3. Obtain a copy of the accreditation certificate from the off site facility.
4. Request a copy of the off site facility’s protocols for further cleaning, packaging, sterilisation, monitoring and a sample copy of a page from its record book – some provide the cycle monitor results with each returned load.
5. Transport all items safely to avoid the containers moving around in the vehicle. Transport the container either on the floor of the vehicle or the boot preferably.
6. Allow the off site facility to perform the packaging as it may be required to reclean according to any specific insurance criteria.
7. Prevent pouches moving freely and tearing by using bubblewrap in the box.
8. Check and record that the pouch indicator (Class 1) has changed on return.
9. Check and record each pouch for dryness and any tears on return.
10. Place results of the cycle if supplied into a record book.
11. Check and record that all pouches have a date and batch
12. A record book is required to place patient’s name against each pack used.
13. If your off site facility is not accredited then seek records of each cycle result. You are responsible for the provision of sterile supplies from that facility in this case.

## **VII. Loading and unloading of the steriliser.**

### **Sterilisation and the drying cycle.**

Steam sterilisation occurs when steam under pressure contacts a surface and releases sufficient heat to that surface over sufficient time to sterilise it.

### **Steriliser settings and water level**

- use the drying cycle to preserve instruments regardless of the load type
- do not alter the time once validation has shown it is the required time
- if there is no printout then a Class 4/5/6 indicator for every cycle is still acceptable
- check the printout after every cycle to ensure it reaches 134-136 Celsius for the time set (most are set for 134 C)

Ensure that manual fill sterilisers receive the specific volume of water in the chamber. Too much water may result in the steriliser not drying the load while not enough causes overheating, damaging delicate items.

### **Loading**

Loading of the steriliser should allow adequate penetration of the contents by steam and allow it to escape from pouches during the drying cycle. A rack is used to separate pouches and keep them upright – some racks allow for up to 14 small pouches but most allow for 6-8 medium sized pouches. Pouches must not touch each other or the wall of the chamber. Pouches can only be placed flat if they do not touch each other and place them so that the paper side is against the tray.

It is preferable not to combine porous (textile) and non porous (instrument) loads but it is commonly done. If using multiple trays, place unwrapped items either below or on the same level as wrapped items to avoid condensate dripping on pouches. Only perforated trays are placed flat.

Hollow ware (bowls etc) can pose a challenge to steam sterilisation by the commonly used downward displacement cycle. Place the dish or bowl on edge to allow air to be displaced. If a number of dishes or bowls are being processed unwrapped together, they may be placed as a stack but spaced by using a piece of textile to allow air removal and steam penetration. Hollow items eg trocars are preferably sterilised in a prevacuum (Class B) steriliser cycle.

### **Unloading**

The door is opened immediately after the drying cycle has finished. The tray with its contents is then removed and placed on a cake rack for cooling the load – do not place the tray on a flat, cool surface as condensation will occur, resulting in wet packs. When cool, check for dryness. Bacteria from moist hands pass through the pouch so hold edges only with dry hands and do not touch hot pouches because the paper is more porous and contamination of sterilised instruments may occur. Record that they are dry and intact.

### **Wet packs**

If moisture is seen on pouches at any stage after opening the door then the cycle has failed and the pouches cannot be used. Reprocess using new pouches. First review loading, load volume, pack density, pouch separation, volume of water and that the drying setting is as per manufacturer's directions.

## **VIII – Settings, monitoring, record keeping and tracking**

### **Settings**

The most common temperature setting used is 134 degrees Celsius. The sterilisation time is determined at annual validation as the time it takes for sterilising conditions to occur inside the challenge pack at validation. If the drying time is adjustable, confirm the manufacturer's recommended time. The printer is set to measure temperature every 60 seconds during the sterilisation part of the cycle. If this is not occurring, have it readjusted. Note that some models cannot be adjusted - use a Class 4,5 or 6 indicator in each load to confirm that each cycle is reaching correct parameters.

### **Essential features of Monitoring**

1. Every load must have a process (Class 1) indicator – the marking on pouch or a piece of steriliser tape are examples. This changes colour on exposure to heat and distinguishes processed from unprocessed loads but does not indicate a successful cycle. For unwrapped loads where a printout is used, use a piece of tape.
2. Every cycle must have a cycle monitor. A printer is required but Class 4/5 or 6 indicators are still acceptable. A data logger without a printer needs to be downloaded and checked after each cycle. Results are entered into a log book against details for that load. Keep printouts/indicators. If you have a new and not yet validated steriliser or a loan unit, then in addition to a printer, use a Class 6 indicator for each cycle.
3. Each load is checked and recorded for dryness and breaches to pouch integrity.
4. Biological testing is not required between validations except in certain situations.
5. Annual service with validation is required and filters need checking six monthly.
6. For Class B (prevacuum) steriliser cycles, testing of both vacuum and steam penetration is a requirement ie daily leak rate test (or weekly if you have an air detector) and a Bowie Dick test/Helix test are required to detect air entrapment. Class B cycle is preferred to Class S cycle for hollow equipment eg trocars/handpieces.

### **Record keeping for each cycle**

A log book is kept which provides the following details about each cycle

- Date and batch of load
- Contents of load eg number of pouches and basic content description
- Class 1 (process) indicator result and result of printer or suitable indicator
- Load checked after processing for integrity – ie. dryness and no tearing
- Signature authorising items able to be released for sterile use

### **Example of setting out of log book**

<b>Date/Batch</b>	<b>Load description</b>	<b>Pouch indicator</b>	<b>Cycle Monitor</b>	<b>Pack Integrity</b>	<b>Authorised For use</b>

### **Tracking for recall**

It is necessary to be able to track the cycle that instruments come from to the patient. The two methods are either placing a label/details from pouch to history or placing details in a procedure book.

## **IX – Storage of sterilised items**

### **Storage Protocol**

1. Transfer pouches for storage to a drawer or cupboard or shelf with doors to protect from moisture and dust. Allow for even rotation of stock by placing the most recently sterilised pouches to the rear.
2. Before removing an instrument for use, check that there is no break in the pouch and that the instrument looks clean and that the process indicator indicates processing has occurred.
3. Do not use “use by” dates but ensure the above criteria have been satisfied.

### **Information notes on storage.**

If sterile instruments are stored on benches near sinks, moisture absorbed by the paper in the pouch allows microorganisms to gain access to the instrument and contaminate it because the paper acts as a wick through which bacteria migrate.

Dust and microorganisms settling on pouches that are incorrectly stored will settle back onto the instruments when they are opened and contaminate them.

A clean labeled plastic container with a lid is an alternative if there are no suitable cupboards, shelves or drawers.

Avoid handling packs with wet hands or gloves as this will contaminate not just the pack required but other touched pouches when accessing a pack.

It is not acceptable to store items on a bench.

Do not break open a pouch by piercing the instrument through the pouch because this redistributes fibres and contaminating microorganism from the external surface to the sterile instrument. Instead, peel back the plastic from the paper as intended.

### **Use by dates**

Use-by dates on sterile supplies are no longer used as long as there is a procedure to keep stock sterile. This is because sterility is event related not time related. If a pouch from a successful cycle is being stored, then as long as there are no tears in the pouch and that it does not come into contact with moisture or dust or has not been dropped, it will remain sterile indefinitely. However, the plastic side of pouches may become brittle over a few months and may split. Always check a sterile pack before opening it.

Hospitals often use “use by dates” if pouches or trays are not stored in an outer plastic cover. However, a General Practice set up is small by comparison and does not involve carting wrapped packs on trolleys such as occurs in a large facility.

## **X. Validation of the sterilisation process – from AS 4815 2003**

### **Overview.**

VALIDATION MEANS TO CONFIRM OR PROVE. This process requires an annual review of current cleaning and sterilising procedures. Testing is also performed at this time to check it is delivering sterilising conditions to the most challenging part of the most challenging load. This includes testing that it kills a standard microorganism placed in parts of this load to confirm loads are being sterilised.

Prior to performing testing, the following review needs to be performed

- Updating of any protocols for the process from initial treatment to storage
- Documentation of ongoing staff education in the procedures they perform
- Steriliser service and maintenance records available and current
- Log book is available that is correctly recording results of every cycle

### **Requirements for validation**

- Book or order the following to be done at the annual service to save costs.
  1. **The Heat Distribution Studies** are required to identify the “cold spot” and only repeated if significant alterations occur eg a new thermostat. A new steriliser should have the results of this test done at manufacture.
  2. Prepare and document your densest load and leave the densest pouch unsealed for **Heat Penetration Studies** ie the penetration time and “Time at Temperature Testing” to be done by the technician.
- You need 7 Biological Indicators and access to a 56 degree C incubator

### **Standard names, tests and equipment for validation (these are the new terms)**

#### **1. OPERATIONAL QUALIFICATION (service and cold spot)**

- The annual service done according to requirements.
- The Heat Distribution Study done by placing temperature sensors over drain and front in an average size empty chamber.

#### **2. PERFORMANCE QUALIFICATION (Penetration studies and spore tests)**

##### **Physical qualification**

- The two tests involved are done in one cycle and are explained below.

The penetration time is the time taken for the middle of the pack to reach the correct temperature once the chamber has reached 134 degrees C. For pouches of 4 or less instruments it is considered to be zero. For dense loads it may be so high that the time setting needs adjusting. It may not register if it is only a few seconds. It is done in the same cycle as the time at temperature test and you should automatically receive results for it as part of the cycle test.

The time at temperature test establishes that your densest pack receives a minimum of 3 continuous minutes at 134 degrees C or 4 at 132 during the holding time and confirms that your steriliser is delivering what you are setting it for.

Both tests confirm physical conditions for sterilisation. The cycle should be checked for dryness as part of validation and any adjustments are then made.

### **Equipment used**

- The technician uses a temperature sensor with two wire probes attached to a temperature recorder. One is placed in the unsealed densest pouch in your densest load. This is then sealed and the pouch placed as close to the cold spot as is practicable. The other probe is placed adjacent to the temperature sensor controller (in the drain). The door is closed (the wires are thin enough to enable the door to seal although a different set up will be required for a prevacuum steriliser) and the cycle is commenced.

### **Microbiological qualification**

This proves that once the steriliser is set as above, it will kill a standard number of challenging microorganisms known as *Geobacillus stearothermophilus*.

- Three consecutive identical loads are run, each with two Biological Indicators (BIs) placed where probes are/were i.e. in the pouch over the cold spot and on the tray over the drain - both BIs may be very close. The first validation cycle may be run with the Physical Qualification cycle although if the time needs to be adjusted, this will need to be repeated and two BIs will be wasted. Three consecutive cycles must be run (no other cycles to be run in between) are run and the first may be run with the Physical Qualification test. This experiment tests identical conditions. After completion of cycle 1, run cycle 2 and 3 with BIs placed in the same positions but without sensors. Interrupt the drying cycle once it has been checked if you wish to save time. However, expect the printout to record fail due to cycle interruption – as long as it has reached expected parameters, this can be overridden for this occasion – it is the sterilisation time which is being checked. The tests are then incubated.

### **Note caramelization of sugars where BI may turn brown**

Some sterilisers operate at a very high temperature during the drying cycle and this may caramelize the sugars in the unwrapped BIs. This can affect interpretation of results and should be repeated. One way to avoid this is to switch off the steriliser after the sterilising part of the cycle and remove BIs when cool.

### **Equipment used**

- After cooling each load, place the BIs in a plastic bag immediately to prevent dust etc entering the holes and post for incubation intact or crush the inner vial as per directions when cool (caution-hot tests can shatter) while placing them in a 56 degree Celsius incubator (calibrated annually) with an unprocessed control. All 7 are incubated in a 56 C incubator for 48 hours.

100% pass is required which means that the 6 processed tests remain purple i.e. no growth whilst the control turns yellow to indicate the batch was alive.

Validation establishes that as long as you don't exceed your densest load and that all other aspects of the process are correct that your load is considered sterile. This needs to be repeated annually, if the steriliser undergoes major repairs and if you wish to increase the density of your original validated load. Validation is repeated for different load types if you wish to use various cycles. Never use an unvalidated cycle.

# Validation Template

## **1. Performance Qualification**

**HEAT DISTRIBUTION STUDIES** *(attach results as evidence if previously done)*

- The cold spot is located.....

## **2. Operational Qualification**

### **Physical Qualification**

**HEAT PENETRATION STUDIES**

- The densest/challenge load is recorded below and positions are referenced. i.e. Position 1 may be next to hinge. Indicate which pack is to be tested.

**TABLE 1**

Rack position	Pouch contents
1.	
2.	
3	
4	
5.	
6.	
7.	

Or  
attach the layout in a diagram.

- **For the service agent to provide results (attach) and for you to complete**

A. Penetration Time =.....(underline this on attached evidence if it is measurable)

B. Attach evidence that the time at temperature test has been done and whether any adjustments to the time settings are required by the user

C. Drying time of .....minutes is recommended by the manufacturer. Is this adequate/inadequate? If inadequate it was altered to.....minutes.

D Indicate if you wish to combine this test with your first BI test cycle YES/NO

Signature.....

- **For staff to complete from service technician's results**

A. Holding Time recommended by manufacturer = ..... minutes

B. Result of penetration time = ..... seconds/minutes

C. 3 minutes at 134 C is required then add penetration time = .....minutes.

D. The result for C must be equal or less than A or an adjustment is required.

Signature.....

- **For staff to complete**

- A. Date of annual validation.....
- B. Identification of steriliser being validated.....
- C. Date of service.....
- D. BI batch number.....
- E. The temperature, time and pressure for validation.....

## Microbiological Qualification

### Preparing and using tests

Label 7 BIs as shown below with marker pen. C is the unprocessed control. Place one each in densest pack in cold spot and over drain and run cycle. Allow to cool before crushing inner glass tube if incubating tests on site. Otherwise send intact for incubation of all 7 for 48 hrs at 56 degrees.

Note -if BIs turn brown after sterilisation, refer to section 3 on validation.

**TABLE 2**

BI number	Cycle number	Position	BI 48 hour Result
1A.	1.	Over drain	
1B.	1.	Challenge Pack	
2A.	2.	Over drain	
2B.	2.	Challenge Pack	
3A.	3.	Over drain	
3B.	3.	Challenge Pack	
C.	Unprocessed	-	

All processed results must be purple and the control yellow for a pass result.

Printer/indicator for each cycle showed PASS. Sign.....

BI remained purple so that its result for each cycle showed PASS. The control changed to yellow also indicating PASS.

Name.....Sign.....

Responsible person to sign off on Validation of sterilisation process

Name.....Signature.....

Date.....

### COMMENTS

## **XI – Steriliser maintenance, service and trouble shooting**

### **Steriliser maintenance**

Annual service is a minimum requirement with filters requiring 6 monthly attention. Validation is performed annually after a service or if major changes have occurred.

There needs to be a maintenance policy for servicing. It should be in the steriliser service folder.

### **Steriliser cleaning**

Refer to the manufacturer's recommendation first. Wipe the outside surface of the steriliser daily with a damp cloth to reduce dust. To keep equipment free of soil build up, wipe chamber, trays and racks daily (standards say weekly) with a damp cloth after the last cycle each day. Wiping reduces build up of mineral deposit and is repeated until no residue appears on the cloth. The door is left open overnight. Some manufacturers recommend use of a specific product for cleaning the chamber - follow directions. If mineral deposit persists, a weak acid such as citric or vinegar may be tried. Drain tank weekly, refill with distilled water.

There needs to be instructions for emptying, cleaning and type of water used. It should be in the steriliser service/maintenance folder or with the steriliser.

### **The steriliser folder**

Keep the following information together.

1. The annual service records.
2. The date of the next service and validation.
3. The contact details of the service agent.
4. Instructions for cleaning, checking filters and maintenance.
5. Dealing with a failed cycle. See below before calling a service agent.

### **Troubleshooting for failed cycles**

- Always repeat cycle with a rewrapped load before proceeding further
- When the class 1 (pouch) indicator fails ask
  1. Was the steriliser turned on? Reprocess to find out.
  2. Is this a new pouch batch? Process one from the old batch if possible
  3. Was this pouch for processing or assumed to be already sterilised?
  4. Did overloading occur such that the pouch did not get very warm?
  5. If the printout passes, then suspect pouch indicator is faulty and return.
- If the printout or class 4,5 or 6 indicator shows a fail
  1. Reprocess load with new pouches and new indicator placed in a pouch.
  2. Call your service agent after first repeating and the results are the same
  3. Do not use instruments from a failed cycle
- If the pouches are wet, the cycle has failed even if the printout has passed.
  1. Reduce load and amount of dense material in each pouch
  2. Ensure pouches are in a rack and unwrapped items are not above them
  3. Ensure the correct amount of water is being used
  4. Ensure pouches are cool before checking
  5. Ensure the warm rack is not placed on a solid surface (use a cake rack)
  6. Ensure the drying time is set as per manufacturers' directions.

## **4. Clinical Waste Management**

### **Defining Clinical Waste.**

Clinical and Related Waste includes clinical, infectious, cytotoxic, pharmaceutical, radioactive and body parts. It is disposed in accordance with EPA guidelines and this may include steam sterilisation, incineration or treatment with chlorine prior to landfill. Waste from General Practice containing blood, body fluids (faeces and urine included only if blood is visible or for laboratory testing or patient infectious), exudates and disposable items in contact with these is considered clinical with a potential to infect. Non sharp clinical waste is placed in labelled bins lined with leak proof bags. These are placed for collection in yellow, labelled bins. Puncture proof sharps bins are used.

### **Legal requirements of Practices**

Practices are responsible for waste until it is rendered safe by treatment and staff should be aware of what treatment is used. If sharps are disposed incorrectly and later traced, there may be a heavy penalty and liability should an injury occur.

Practices need a certificate from their waste company showing compliance with the law regarding disposal and a copy of the collection and disposal process. Transport from a Practice must be to a disposal point and not to an intermediate collection point unless a licence has been obtained from the EPA specifically for storage of that waste. A licensed collector trained to decontaminate spills transports waste from its origin to a point of disposal in a vehicle properly fitted to secure its load.

### **The most commonly asked questions about clinical waste.**

- Urine and faeces? These are clinical wastes if blood is visible, if for laboratory testing or from a patient infected with an organism transmitted by these fluids.
- Sanitary napkins/bandages? This waste may be no more infectious than that from a public area disposal bin but the standard allows for safe handling by staff and requires segregation. The rationale may be that patients with infection are likely to over represented in a health care facility - therefore, waste poses a risk.
- Discarding blood tubes? Dispose to sharps container to reduce spillage/leakage.
- Should only needles be disposed as sharps? A sharp is any item, which can pierce skin. It includes blades and glass. Consider sharps as able to pierce bags.
- Should needles be disconnected from the syringe? This is not recommended unless by an approved safe method - eg with one hand behind your back
- Expired Pharmaceuticals? Check with the collector. Bulk pharmaceuticals should be packaged in a labelled box for separate treatment.
- Fluids? Drainage bags are double bagged or placed in 20 litre buckets with lids.

### **Improving segregation of waste.**

Clinical waste treatment and disposal is expensive and not environmental. Auditing shows that clinical waste bins contain significant volumes of non clinical waste eg handtowel, packaging and office paper. In General Practice, clinical waste should include dressings, bloodied material, gloves, specula, body fluid stained textiles and tongue depressors. Consider items causing public offence as clinical waste eg vomit. If no clinical waste is generated in the consulting room, provide only a general waste bin for handtowel/tissues and packaging. If clinical waste is generated, provide small, kitchen tidies for disposable specula/gloves and place on a bench. Store waste in lockable area inaccessible to the public.

## **5. Sharps/splash injury and risk of infection.**

### **How sharps injuries occur**

1. Compressing overflowing sharps into a bin resulting in needles piercing bin.
2. Cleaners tipping sharps from containers into bags or other sharps bins.
3. Needles left around entrances to clinics, in meter boxes, patients toilets etc.
4. Staff disposing of sharps in bandage which sticks to the neck of the bin.
5. Staff not aware that metal pull caps from vaccines etc are sharps.
6. Staff not able to see opening of sharps bin (sharp may be protruding)

### **Initial treatment of a sharps injury or body fluid splash**

- Wash injury with soap and water or flush membranes with water
- Gentle pressure may be applied but do not squeeze
- For skin, do not use bleach but apply antiseptic for normal first aid

### **Probability of contracting HBV, HCV or HIV**

- From a source with HBV – varies from 3-30% depending on status of source
- From a source with HCV – approx 2%
- From a source with HIV – approx 0.3%

## **Hepatitis B Infection**

This spread is via blood, sexually or mother to baby. Saliva may contain HBV but insufficient to be infectious. HCWs are more likely to have HBV than general population. An extremely small, just visible volume of blood may transmit HBV. Many infected people cannot recall a specific injury - entry to the blood via a scratch or splash etc. It can survive at least a week in dried blood but there have been no documented case of infection from the environment ie. syringes on beach, indicating other factors. Almost 1% of the population carries HBV. It appears more difficult to transmit HBV from a carrier than from someone who has the infection. HBV infection is preventable via immunisation which is more than 95% effective.

## **Hepatitis C Infection**

HCV spread appears confined to blood and mother to baby at birth. If there is exposure to infected blood during sexual activity then infection may occur. In a health setting, only hollow bore needles appear to carry transmission risk. There are no documented cases of environmental transmission even though HCV may remain infectious for at least two weeks in a favourable environment. The carrier rate is estimated to be 3% and rising.

## **HIV infection.**

It is spread by infected blood, sexually and from mother to baby. While unknown, it appears a visible amount is needed. The particles are stable and remain infectious at room temperature 2-4 weeks. There has been no known environmental transmission of HIV. There are 23,000 HIV carriers in Australia. Risk of transmission from needle stick injuries from an unknown environmental source is less than 1:10,000,000. If the HCW is exposed to sufficient volume of fresh blood from a positive source, the risk is 0.3% ie 1 in 300 but prophylaxis within 2 hours can reduce this to 0.1%. If the source is positive, the HCW will receive a week course of anti retroviral therapy.

## **6. Staff Immunisation**

### **What extra risks are Practice staff exposed to?**

Staff working in General Practice are in increased contact with various infectious diseases. Therefore, it is important that information is supplied to staff and that there is a staff immunisation program at commencement of work. Staff should also be familiar with the immunisation schedule offered to the whole community because this has changed in the last 5 years. This includes that offered to travellers to different parts of the world, new combinations offered to babies and the trend to killed vaccines for some infections.

### **Vaccines for Health Care Workers.**

Refer to the 8<sup>th</sup> Edition Immunisation handbook for immunisation of health care workers and use the schedule to develop a staff immunisation program. Ask the health department to supply HCW immunisation record cards.

It should be assumed that all Practice staff have direct contact with blood and body substances. This means they should receive immunisation against Hepatitis B and be tested post immunisation to determine if they have produced antibodies. Some 10% of those immunised with a course of three doses of vaccine for Hepatitis B will not produce detectable antibodies. They are given either

- 2 doses, one in each arm or
- a further three doses one month apart (more cumbersome)

Almost half will respond. Those who fail to raise detectable antibodies should be tested for previous exposure to HBV. If found to be still unprotected they must be given HBIG within 72 hours of a needlestick injury.

Other recommended immunisations are

- Hepatitis A,
- Measles/Mumps/Rubella (for those born from 1966 or who have not had both measles containing vaccines
- Polio
- Chicken pox (varicella) if no history or negative serology
- ADT (adult diphtheria tetanus).

Staff are not at any more risk from meningococcal disease but if they were born since 1984 then they should receive the free immunisation. Those aged between 20 – 25 are in a risk age group but not because of their working environment.

The Influenza vaccine is important where staff are in contact with elderly patients because infection in non immune elderly patients may be fatal.

There are cases where these staff have contracted blood borne infection. Consider protecting them against HBV.

### **Boosters to HepB**

There is evidence that the hepatitis B vaccine confers long term immunity and there is no need for boosters normally. However, some professions have their staff blood tested at intervals of two years to ensure antibody levels are protective and a booster may be provided if this level drops to below that considered necessary for protection. Staff need to keep up to date with their normal community based immunisation schedule.

## **Products and Contacts**

### **1. Items available from supermarket, hardware or stationer.**

1. Two pair kitchen gloves (latex for washing, vinyl for drying eg Silk Touch)
2. Toothbrush for brushing instruments - (Tek can be steam sterilised)
3. Exercise book or folder for recording cycle results
4. Solvent based felt tip marker eg laundry marker pen (non-toxic)
5. Plastic containers with lids and washing bowl
6. Safety glasses (available from hardware stores- \$15)
7. Plastic apron (needs to provide adequate cover at front) – pinafore style
8. Liquid soap for handwashing
9. Paper towel for drying hands
10. A toast rack for placing pouches upright in chamber
11. A cake rack for placing trays to cool

### **2. Other required items the Practice may have or may obtain from medical suppliers**

1. Blueys plus lint free towel to place cleaned, wet items on
2. Lint free towel for drying instrument - reusable Aquasorb or disposable Senset
3. Commercial labels eg Meditrak instead of marker pens for pouches
4. Detergent such as Clinidet or Sonidet. Endozyme for endoscopes etc
5. Pouches for wrapping instruments.
6. Class 4,5 or 6 indicators if there is no printer
7. 7 x BIs for annual validation and access to a 56 degree Celsius incubator.
8. Suitable antimicrobial handwash - 4% required for surgical procedures
9. Hospital Grade disinfectant for some spills
10. Vomit bags
11. Body fluid spill kit
12. Collection bins and sharps containers for clinical waste
13. Immunisation cards from DHS

### **3. Contacts details if not available from your supplier**

1. Sonidet detergent and Viraclean Disinfectant by Whiteley. 1 800 257 352.
2. Clinidet detergent and Aquasorb towel by Majac Medical. 07 3889 8008
3. Blueys and low lint towel eg versatowel Kimberley Clark. 03 9550 8088
4. Pouches for sterilising -Fiona Richards EBOS group 8863 6368
5. Lint free senset disposable towels EBOS group – Sally Wood 8862 6373
6. Endozyme, Avagard Handrub, Comply Class 5 and Biological Indicators from 3M. 1300 363 878
7. Embags by Frontline Innovations. 1800 66 77 22
8. Microshield and Milton by Johnson and Johnson
9. Zeomed Biohazard spill kit – Enware 1800 671 864
10. SteriCorp for waste containers and collection – Kylie Moss 0439 885 336
11. Immunisation cards (HCW) from DHS 1300 882 008

### **Steriliser service agents**

1. **Siltex (Australian manufacturer) Phone Daryl Smith 03 9570 6222.**
2. **Calitec. Craig or Dale for servicing or validation support. Phone 9484 8509**
3. **Select Technologies. Phone Sean Mehegan 0417 255 355**