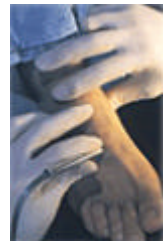


National Infection Control Guidelines for Podiatrists

prepared by the
Australasian Podiatry Council
on behalf of the
Podiatrist Registration Boards

version one - September 2005



Introduction

This document outlines recommended practices and procedures for infection control in the podiatric setting. It has been compiled from a number of pre-existing state and national documents whose content is based on fundamental infection control principles.

The key sources of reference for this document include:

- the Australian Government;
- the Communicable Diseases Network Australia (CDNA);
- the National Health and Medical Research Council (NHMRC);
- State Podiatry Registration Boards, in particular "Infection Control Policy and Procedures for Podiatrists" Podiatry Board of South Australia, September 2004;
- Standards Australia;
- State / Territory legislation, regulations and guidelines; and
- local requirements.

The primary aim is to prevent the transmission of infectious diseases in the podiatric setting.

According to the Australian Government, Department of Health and Ageing:

"Successful infection control is based on good hygiene around a range of practices that arise from identifying hazards and implementing risk management for the hazards. This involves understanding:

- the infectious agents;
- the work practices that prevent the transmission of infection in different settings; and
- management systems that support effective work practices."

Source: Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting (CDNA,pg iii) <http://www.icg.health.gov.au>

The 'National Infection Control Guidelines for Podiatrists,' have been written to reflect the principles behind successful infection control. It serves as an essential tool for all podiatrists in the implementation of infection control strategies.

This document is comprehensive but not exhaustive. It should be read in conjunction with:

- infection control guidelines for the prevention of transmission of infectious diseases in the health care setting. Communicable Diseases Network Australia (January 2004). (To be referred to as the CDNA, ICG throughout this document) This document was prepared under the auspices of the Communicable Diseases Network Australia (CDNA) and has been endorsed by the Australian Health Ministers' Advisory Council. The full document is posted on the Australian Government Department of Health and Ageing website (<http://www.icg.health.gov.au>). Updates will be posted on the website as amendments are made;
- Standards Australia, AS/NZS 4815 (2001) [*currently being updated*] Office based health care facilities not involved in complex patient procedures and processes – Cleaning, disinfecting and sterilising reusable and surgical instruments and equipment;
- Standards Australia, AS/NZS 4187 (2003) Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in Health Care facilities; and
- State / Territory legislation, regulations and guidelines. If discrepancies exist between state and national infection control legislation, regulations or guidelines, the former takes precedence.

How to use this document

The information in this document is presented in the following sections :

Section 1	Principles of infection Control	This section overviews the fundamental principles of infection control on which the recommended practices and procedures are based. Key strategies are introduced.
Section 2	Effective infection control work practices and procedures	This section is about applying infection control in podiatric practice. Important practices such as; hand washing, the use of protective gear, clinic layout, workflow and practices relating to patient consultation, are discussed. Waste disposal and sharps management complete the section.
Section 3	Processing re-useable instruments and equipment	This section addresses sterilising re-useable instruments. Initial decontamination, cleaning, preparing instruments for sterilisation, storage and transport are covered. Using a steriliser is discussed including the types of machines and requirements for monitoring their efficacy.
Section 4	Cleaning and maintenance of the podiatric clinic and equipment	This section details recommended procedures for cleaning and maintenance of podiatric equipment from an infection control perspective.
Section 5	Quality management	This section considers the importance of maintaining high infection control standards in podiatric practice and strategies to facilitate this.
Section 6	Risk management	This section identifies the importance contingency plans and preventative measures in protecting staff from exposure to infectious agents.
References, Glossary and Appendices		The document concludes with sources for further information, a definition of key terms, and additional information appended as required.

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Preface

Every podiatrist has a legal, moral and ethical responsibility to their patients and staff to provide an effective infection control program, in order to prevent infection and cross infection. The intention of this document is to provide a national set of infection control guidelines, specifically written to inform podiatric practice. Whilst infection control is a changing area, given the advancement of technology, regulatory changes and microbial evolution, these guidelines reflect current best practice at the time of writing.

The 'National Infection Control Guidelines for Podiatrists,' have been prepared through a broad process of consultation. The Australasian Podiatry Council has worked in conjunction with State Podiatry Registration Boards, whose role it is to regulate and monitor the standards of podiatric practice. These infection control guidelines, along with any state legislative and regulatory requirements, form the benchmark for infection control in podiatric practice.

Section 1. Principles of infection control

Salient points

- **many infectious agents are present in the podiatric clinic which may lead to patients or staff acquiring disease;**
- **it is essential in preventing the transmission of infection that; basic infection control strategies, quality management practices and effective work practices, are adopted;**
- **standard precautions are work practices adopted, regardless of perceived infectious risk, to achieve a basic level of infection control; and**
- **additional precautions are sometimes required where standard precautions alone will not contain infectious agents.**

1.1. Principles of infection control

Providing a safe environment for podiatry patients and staff of podiatry practices is a fundamental goal of quality podiatric care. Many infectious agents are present in the environment which can lead to the transmission of disease. Understanding key principles of infection control provides a basis for devising strategies to minimise the risk of cross infection.

Infection can be defined as “a condition in which all or parts of the body is invaded by a pathogenic agent (bacteria, protozoan, virus) which multiplies to produce local and/or systemic injury. An understanding of how microbes are transmitted provides a means to prevention.” (The Podiatrists Registration Board of Victoria Infection Control Manual, Section 2-1)

For infection to spread three basic elements are required:

- source of infective organisms;
- susceptible host; and
- a means of transmission of the micro-organism.

Patients may contract infection or disease from:

- themselves or from other patients;
- podiatry staff;
- instruments and equipment; and
- the practice or practice environment.

Podiatrists, podiatry assistants and office staff may contract infection or disease from:

- themselves or from contact with patients;
- podiatry staff;
- instruments used on patients; and
- the practice or practice environment.

Infection may spread by the following routes:

- inhalation;
- direct physical contact; and
- ingestion.

The main principles in preventing transmission of infection are to:

- identify all potential sources of infection; and
- care for patients and staff in such a manner that risk of transmission of infection is minimised.

Many micro-organisms exist in our environment and live on and within the human body. Most are harmless commensal organisms however some can cause disease. These pathogens can move to other areas of the body or to a different host and if able to become established can cause harm. Some pathogens are particularly aggressive and some people are more susceptible to infection than others. These factors must be considered in the clinical situation when addressing the complexity of issues surrounding infection control.

Maintaining a safe environment is everybody's responsibility

The following infection control strategies aim to interrupt the cycle of transmission of infection. Adhering to these can reduce the risk of infection.

Routine measures for infection control include:

- standard and additional precautions ;
- aseptic technique;
- safe handling of sharps;
- utilizing single use equipment ;
- reprocessing of reusable instruments;
- cleaning of the practice environment;
- appropriate use of antiseptics and disinfectants; and
- staff health and immunisation.

A two tiered approach is recommended by the Communicable Diseases Network Australia in promoting high-level protection to patients and staff (CDNA, ICG Part 1; 2-2). Infection control strategies adopted in podiatric practice should be based on the use of standard precautions as a minimum and supplemented by additional precautions where indicated. The later situation would occur when standard precautions alone are deemed insufficient to prevent cross infection.

Further information

For further information on infection control principles, please refer to the Communicable Diseases Network Australia (CDNA) document, "Infection Control Guidelines (ICG): for the prevention of transmission of infectious diseases in the health care setting." January 2004; *Web site:* <http://www.icg.health.gov.au>

1.2. Standard precautions

Standard precautions are work practices adopted to achieve a basic level of infection control that apply to the care and treatment of all patients regardless of their perceived infectious risk.

This is based on the premise that all blood and body fluids are potentially infectious.

If properly conducted, standard precautions should be all that is required to prevent the transmission of most infections.

Standard precautions should be implemented *at all times* as a *minimum requirement* for infection control.

Standard precautions are detailed in this document and include:

- aseptic technique;
- hygiene practices such as hand washing;
- the use of personal protective equipment ;
- appropriate clinical layout and workflow;
- appropriate clinical work practices;
- protocols for waste disposal and sharps management;
- protocols for processing re-useable instruments and equipment; and
- appropriate practices for cleaning and maintenance of the podiatric clinic and equipment.

1.3. Additional precautions

Additional precautions are sometimes required *in addition* to standard precautions.

These strategies are designed to prevent the spread of infection to others from patients, known or suspected to be infected or colonised with infectious agents, that would not be contained by standard precautions alone. This includes infections transmitted by respiratory secretions, or in the case of an open or colonized wound to prevent cross infection to other patients or to another site on the same patient.

Additional precautions are used when dealing with patients who have airborne diseases such as active TB, Chicken Pox, Influenza and Measles.

Also included are significant infections with drug-resistant bacteria, such as:

- Multi Resistant Staphylococcus Aureus (MRSA) where the open wound may be in contact with the treatment site; and
- Vancomycin Resistant Enterococcus (VRE) (eg via faecal contamination), in a hospitalised, or long-term care patient.

Where required, additional precautions include:

- deferring treatment until infectious state is resolved;
- use of a separate waiting area or placing patient at the end of treatment lists to protect other patients in the waiting area [airborne infections] and to allow more time for decontamination/clean up [MRSA or VRE colonized];
- patient and podiatrist wearing additional protective equipment such as masks; (P2/N95 or equivalent mask), gloves and single use gowns; and
- appropriate cleaning regimes for the patient environment .

Note: "Additional precautions are not required for patients with blood borne viruses, such as HIV, hepatitis B virus or hepatitis C virus, unless there are complicating infections such as pulmonary tuberculosis" (CDNA, ICG, Part 1; 2-5)

Further information

For further information about specific diseases or requirements for Additional Precautions refer to local hospital/facility guidelines or contact the Department of Health and Ageing.
(Web site: <http://www.icg.health.gov.au>)

1.4. Aseptic technique

(Refer also to: Hand washing)

A key component of standard and additional precautions, aseptic technique refers to practices that:

- reduce the number of infectious agents;
- prevent the transmission of infectious agents; and
- render and maintain objects and areas as free as possible from infectious agents.

Techniques to maintain asepsis can be categorised into 'clean' and 'sterile'.

Clean Technique

Clean technique refers to practices that reduce the number of infectious agents and should be used for routine, non-invasive procedures such as debridement of skin and toenails as well as dressing of ulcers.

The procedures should include:

- personal hand washing to reduce the numbers of infectious agents on the skin;
- the use of barriers to prevent transmission i.e. gloves, clinical barrier sheets;
- cleaning procedures to prevent transmission; and
- reprocessing of instruments and equipment between uses.

Aseptic (or sterile) technique

Aseptic techniques are practices designed to render and maintain objects and areas as free from microorganisms as possible.

Aseptic technique should be used for invasive procedures including any surgery for ingrowing toenail or superficial skin lesions such as plantar warts.

These sterile procedures are generally regarded as appropriate to be performed in a suitably equipped podiatry practice.

The concept of the 'sterile operative field', which has been practised for many years by operating room personnel, should be adopted by all practitioners undertaking invasive procedures.

Aseptic technique in podiatrist rooms requires the following:

The defined radius of the operative area should be prepared for the procedure by:

- removal of unnecessary items; and
- cleaning of procedural surfaces (Refer to Table six).

The area designated, as the operative field:

- must be covered with sterile drapes ;
- only sterile instruments, dressings and medications to be placed within this field;
- the site for surgery must be prepared (see Skin preparation); and
- a circulating assistant who is 'un-scrubbed' should support the podiatrist and surgical assistant if required.

A surgical scrub must be performed prior to donning sterile gloves (see Hand washing).

Podiatrist and assistants:

- performing surgical procedures must have appropriate training in surgical technique;
- should be vaccinated against hepatitis B;
- must wear protective eyewear, surgical masks, cover any beads and tie back and cover; hair with cap. A waterproof apron may be required;
- who are 'scrubbed' must confine contact to sterile articles and operative area;
- should not perform exposure-prone procedures if they are: human immunodeficiency virus antibody positive; hepatitis B e antigen positive and / or HBV DNA positive at high titres; or hepatitis C virus antibody positive and HCV RNA positive. (CDNA, ICG, Part 3; 24); and
- with dermatitis or skin wounds should be excluded from operating.

Podiatrists performing any surgery involving deeper structures such as tendons, joint or bone should be undertaken in a dedicated operating room with trained staff and support systems, such as a day surgery or hospital facility, in accordance with governing legislation, regulations and guidelines.

Podiatry practices undertaking this type of surgery 'on site' must comply with all the relevant guidelines and Standards for Operating Theatres and Day Surgery Units. (ACORN)

 **Further information:**

The following documents and guidelines are recommended reading:

- Infection Control in Surgery published by the Royal College of Surgeons (RACS1998); and
 - The Australian Confederation of Operating Room Nurses (ACORN) Standards Guidelines and Policy Statements - (May 2002 and updates)
-

Section 2. Effective infection control work practices and procedures

Salient points

- **“hand washing is the single most effective hygiene practice for minimising health care associated infections”;**
- **“gloves are not a substitute for hand washing”;**
- **hands must be washed and dried before and after significant contact with a patient, after any activity which is likely to cause contamination and after removing gloves; and**
- **hand washing facilities, including clinical hand basins and suitable products, must be readily available in all consulting areas.**

Source: CDNA, ICG Part 3; 11 & 12)

2.1. Hand washing

(Refer also to: Standard precautions and Risk management)

Hand washing is considered the most important hygiene measure in preventing the transmission of health care associated infection. (CDNA, ICG, Part 3; 12) The technique for hand hygiene, including amount of solution, duration of procedure and the products used, must form part of the in-service program of the practice.

Hand washing and drying must be performed before and after significant contact with a patient and after any activities likely to cause contamination (such as direct contact with blood or body substances). Hand washing must also be performed after removal of gloves as gloving is not a substitute for hand washing.

Situations when hand washing must occur are:

Before:

- starting work;
- eating;
- using toilet facilities;
- delivery of injection;
- contact with wounds; and
- contact with patients with depressed host resistance.

After:

- direct contact with body secretion(s);
- handling objects/materials soiled with body substances;
- removing gloves;
- contact with wounds;
- emptying drainage bags;
- fitting or touching a mask;
- personal hygiene after toileting;
- blowing the nose;
- smoking;
- touching your face;
- finishing work; and
- eating.

Between:

- contacts with different patients or different procedures on the same patient

(Source: The Podiatrists Registration Board of Victoria Infection Control Manual, Section 2-2)

Intact skin is a natural defence against infection. Cuts, abrasions or lesions of the skin are a possible source of entry for pathogens and must be covered by a water resistant, occlusive dressing whilst working.

The wearing of jewellery (including wedding rings and wristwatches) on hands or forearms in routine practice is somewhat contentious. This is due to the unestablished potential for increased bacterial counts. During invasive procedures jewellery must not be worn. Nails must be kept short and clean. Artificial nails, nail polish or nail decorations should not be worn as they have been found to harbour potentially infectious micro organisms.

 **Further information:**

For further information on the use of jewellery and artificial nails / nail polish, refer to the CDNA, ICG, Part 3; 12-3.

Hand washing technique

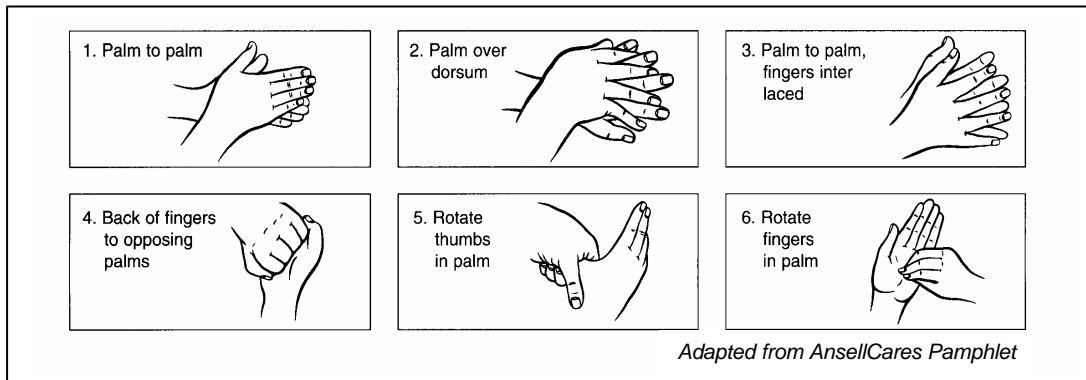
Routine hand washing

In order to facilitate hand washing, sleeves should be above the elbow.

Then, follow the steps pictured below rubbing vigorously for 10-15 seconds

Wash all surfaces: Backs of Hands, Wrists, between fingers and under nails

Figure one: Routine hand washing technique



Surgical hand washing

Shall be performed for any procedure that involves penetration of normally sterile tissues. The surgical hand wash technique shall follow a standardised procedure.

Table one provides further detail on hand washing.

Further information:

For further information on hand washing techniques, refer to the CDNA, ICG, Part 3; 12-1.

Table one : Hand washing techniques / alcohol gel / hand care

Type of hand wash	Washing Technique	Duration	Drying	When
Routine	Remove jewellery Wet hands thoroughly and lather using mild soap Rinse under running water Do not touch taps with clean hands	10-15 seconds	Pat dry using paper towel or clean cloth towel	Before eating. Before and after patient treatment Before and after routine glove use. After handling instruments and equipment used in treatment procedures
Aseptic procedures – non surgical	Remove jewellery Wet hands thoroughly and lather using an antimicrobial soap or skin cleanser Rinse under running water Do not touch taps with clean hands	One minute	Pat dry using paper towel	Before any non-surgical procedure that requires aseptic technique – eg debridement of ulcer or change of surgical dressing
Aseptic procedures -Surgical	Wash hands thoroughly using an antimicrobial soap or skin cleanser. Rinse under running water keeping hands above elbows No touch techniques	First wash for a surgical session- five full minutes. Subsequent washes - three minutes	Dry well with sterile hand towel	Before any invasive surgical procedures. Before donning surgical gloves
Alcohol rub, gel or rinses	Dispense a measured amount on to <i>clean</i> dry hands and rub into all surfaces of the hand until hands are dried	8 - 10 secs	Rub until dry on hands	For routine hand decontamination when hands are not visibly soiled – i.e. accessing items outside treatment zone. When hand washing facilities are not available – home visits

Hand washing facilities

Sinks for the purposes of hand washing should:

- be readily accessible in the clinical area;
- be dedicated for the purposes of hand washing not for other cleaning functions ;
- have elbow control or non-touch taps;
- run hot and cold water; and
- be accompanied by liquid hand wash (see hand washing for details) and disposable paper or single use clean cloth, hand towels.

Hand washing and hand care products

Mild soaps that are colour and perfume free are advisable for routine hand washing.

Mild liquid soap dispensed from a container with a disposable cartridge and nozzle are recommended. Where possible a touch-free dispenser is preferred. Any pump mechanisms should be carefully cleaned. Refillable containers have been identified as a potential source of contamination as bacteria can be harboured within products, therefore replaceable containers are recommended.

Oil based hand creams are not suitable to be used when latex gloves are worn as the oil breaks down the latex. Some hand creams are not compatible with chlorhexidine and should be checked prior to use.

Antimicrobial products used for hand washing or cleansing in the practice setting should be TGA [Therapeutic Goods Administration] approved and are advised for use prior to aseptic or surgical procedures only.

Products recommended for therapeutic hand care use on the Australian market, must display an AUST L or AUST R number on the label for recognition.

Hand care

Repeated hand washing and the wearing of gloves can cause irritation or sensitivity.

Following the recommended hand washing technique and using suitable hand care products can minimize the risk of developing problems.

Scrub or nail brushes should not be used routinely as they may result in abrasion of the skin and may be a source of infection.

A medical practitioner should assess all ongoing skin conditions. Cuts and abrasions should be covered by a water proof dressing and changed as required.

Use of alcohol gel - for 'clean' hand decontamination

Alcohol gels may be used when hands are not visibly soiled:

- select a mild product that has moisturizers and emollients and no added antibacterial product, colour or perfume;
- the gel is applied to dry hands and should cover all surfaces of the hand – rub until product dries on hands;
- the hands must be washed with soap and water if soiled and at least every 6th application of the gel to remove product and glove residue build up;
- alcohol gels should only be used in combination with powderless gloves; and
- alcohol gels should not be used when skin is cut or broken.

Alcohol gels may be used when:

- accessing items outside treatment zone;
- hands are dry and/or irritated from contact with water and hand washing product; and
- when hand-washing facilities are not available such as during home visits or when working alone in a nursing home or care facility.

2.2. The use of personal protective equipment

(Refer also to: Risk management; and Workpractices and procedures)

Salient points

- **podiatrists should have access to a range of personal protective equipment which meets Australian Standards and is appropriate for the intended use ;**
- **gloves should always be worn where there is a risk of exposure to blood or body fluid;**
- **protective eye wear or face shields should be worn if there is a risk of splashing, splattering or spraying of blood or body substances;**
- **suitable masks should be worn if there is a risk of splashing, splattering or spraying of blood or body substances or where airborne infection is a threat;**
- **plastic gowns or aprons should be worn to protect the skin and clothing from contamination ; and**
- **in selecting PPE the podiatrist should consider the:**
 - **likelihood of exposure to blood or body substances;**
 - **amount likely to be encountered;**
 - **type of body substance involved; and**
 - **probably route of transmission of infectious agents.**

Source: CDNA, ICG Part 3; 13)

Personal protective equipment [PPE] and clothing can protect the worker from exposure to blood and body fluids.

PPE should be readily available to all staff and comply with relevant Australian Standards.

The PPE made available should be appropriate for the intended podiatric use. Selection of the particular type of PPE required is at the professional discretion of the podiatrist and must be made in consideration of practice policies and occupational health and safety regulations.

PPE includes items such as gloves, gowns and aprons, facemasks and eyewear.

Most Personal Protective Equipment is single patient use and must be disposed of immediately after use.

Personal protective equipment is required in the following situations:

- when there is a risk of exposure to blood and other body fluids secretions and excretions regardless of whether they contain visible blood, through splashing, splattering, spraying or other physical contact;
- contact with non-intact skin, including ulceration and skin rashes;
- contact with mucous membranes; and
- the potential for airborne infection exists.

The type of equipment required depends on the nature of the procedure being performed and should be selected prior to each task.

When working outside the practice setting, on home visits, in hospitals or in nursing homes the podiatrist should confirm the availability of, or carry and use personal protective equipment appropriate to protect from any hazard that may be encountered.

Gloves

Hands should always be washed before and after using gloves as a break in the glove may be present or occur during the consultation, thus creating a hazard.

Gloves should be selected for comfort, fit, feel and for the planned use. Gloves should be changed after each patient procedure or during treatment of the same patient if separate procedures are being performed and there is a risk of infection from one part of the body to another.

1. Sterile Disposable Gloves

- are used for all surgical and sterile procedures ; and
- must comply with AS/NZS 4179.

2. Non - Sterile Disposable Gloves

These gloves are appropriate for most general podiatry treatments:

- must comply with AS/NZS 4011;
- should be worn if there is a likelihood that hands will be contaminated with blood or body fluids;
- should be changed after each patient procedure or during a procedure if contamination occurs; and
- should be removed as soon as procedure completed.

Powder free gloves are preferred, as the powder has been noted as an irritant to hands and as a factor in latex sensitivity and allergy.

3. Utility Gloves

Utility gloves are used for cleaning purposes such as cleaning of instruments. They offer more protection from penetrating injury and chemicals than non-sterile disposable gloves.

Good quality utility gloves with protective linings are recommended for comfort and to absorb perspiration. Alternatively, clean cotton gloves can be worn under the utility glove.

Utility Gloves should be:

- labelled with the user's name, as each person should have his or her own gloves;
- washed in water and detergent after use then rinsed well and hung to dry ; and
- replaced when showing wear or deterioration.

Masks

Masks should be well fitted to effectively cover the mouth and nose, in accordance with manufacturer's guidelines. Masks should be worn during any sterile procedures, drilling of toe nails where dust is created, where a risk the transmission of airborne infection exists or during procedures where there is a risk of spraying or splashing of blood / body fluids.

Surgical masks

Surgical masks are used for surgical or operating room procedures and are single use only.

Masks must:

- comply with AS 4381 –1996-7;
- be worn and fit as the manufacturer intended
- not be touched by hand when on;
- be removed by touching strings or loops only; and
- be changed if moist or visibly soiled.

Fluid repellent deflector masks

Splash resistant masks should be worn when *moist or wet nail drilling* is undertaken to protect against aerosols and splatter of fluid. Most surgical masks are splash resistant.

Dust filter masks

Dust filter masks are recommended for use during nail drilling. Surgical masks generally are not suitable.

A quality, reusable respirator mask that fits firmly to the wearer's face is recommended. Reusable masks should be identified for the wearer and stored clean and protected from environmental contamination between uses.

Eye protection

Eye protection (glasses, goggles, face shields) can prevent blood and body fluid splashes from entering the eye.

Staff may be at risk of infection from eye splash or spray onto the conjunctiva, particularly with viruses such as Hepatitis B, C and HIV.

Protective eyewear also safeguards the wearer from penetrating eye injury.

Protective eyewear, goggles or over shields should also be worn in the instrument decontamination area to protect the eyes and mucous membranes from splashes and sprays.

Eye protection should cover the whole eye socket and also provide side protection and be worn and fitted in accordance with manufacturer's guidelines. Protective eyewear should be discarded after it has been worn if not re-usable, otherwise it is to be cleaned as per the manufacturer's instructions.

Prescription glasses, fashion frames and contact lenses do not offer adequate coverage and side protection. Contact lenses may even increase the risk of exposure if hazardous fluids penetrate under the lens.

Gowns and plastic aprons

Gowns and plastic aprons are designed to protect clothing from contamination by blood or body fluids.

Plastic aprons used for casting, orthosis or instrument decontamination should be designated for use in those areas only.

Gowns and plastic aprons

- should be worn if contamination is likely;
- may be reusable or disposable single use;
- reusable aprons should be stored, clean and dry; and
- comply with AS 3789.2 and AS 3789.3.

Sterile surgical gowns

Sterile pre-packed surgical gowns should be used for all invasive surgical procedures requiring a sterile field. This generally does not include the types of procedures being undertaken in a podiatry practice such as ingrowing toenail surgery or excision of superficial skin lesions where the use of sterile gloves and non-sterile protective gowns and aprons are appropriate.

When sterile surgical gowns are used they should be impermeable to fluid strike through, cuffed at the wrist, and able to be secured to cover all underclothing.

A plastic apron may be worn under the surgical gown to help prevent strike through contamination of underclothing.

Any protective clothing contaminated with blood or body substances should be removed and either disposed of or bagged for laundering as soon as possible.

Uniforms

Clothing worn by podiatry staff should be clean, comfortable, in good condition and suitable for the type of work being done.

All clothing, uniforms and laboratory coats should be freshly laundered and changed if soiled.

When undertaking podiatry procedures short-sleeved clothing facilitates hand-washing procedures and reduces the likelihood of direct contact and contamination of the clinical field.

Protective waterproof gowns or aprons should be worn when splash, spray or contamination of clothing is likely.

Footwear

Footwear should be enclosed and of a design that provides protection from injury, for example if sharps are dropped.

2.3. Clinical layout and workflow

(Refer also to: *Cleaning*)

Salient points

- **a suitably designed podiatry clinic is important to minimising the risk of transmission of infection;**
- **the workplace should be well lit, ventilated (in accordance with AS 1668.2 or State/ Territory guidelines), clean and well organised;**
- **the workplace should be designed to allow for efficient routine cleaning;**
- **to help achieve this, eliminate inaccessible areas that accumulate dust and soil and install easy to clean fittings and fixtures; and**
- **workflow should be from clean areas to contaminated areas.**

Layout

The layout of the workplace should be organised so that sterile, clean and soiled functions (including instruments and equipment) are separated. Work areas should be clearly identified for their dedicated purpose and free access maintained at all times.

There should be enough space to accommodate all necessary equipment.

Separate areas should be allowed for:

- treatments;
- waiting room;
- clerical, administrative and staff room (for eating and staff break time);
- instrument decontamination, packaging and sterilisation;
- adjustment or manufacture of orthoses; and
- storage for clean and sterile stock and equipment.

The workplace should also include space for handling and storage of waste and should be designed to minimise the risk of injury.

Clerical areas

Including writing desks, records, telephones, xray viewers, all need to be clearly identified and separate from clinical or instruments decontamination areas.

Clerical areas should be:

- cleaned regularly;
- uncluttered; and
- not contaminated during treatment .

Computers in the clinic

Operators should not access computer keyboards during treatment procedures.

Keyboards should only be accessed with clean hands and should be covered or placed in a drawer if in the immediate treatment area.

Access to computers may be facilitated by the use of pre-formed plastic film covers that can be wiped over.

Cleaning of the keyboard cover must be part of the routine between patient cleaning and the treatment field.

Workflow

Organise the clinical workplace so that workflow moves from clean to contaminated areas. Ensure that clean instruments and patient care items are kept separate from used items. Ensure that contaminated equipment does not enter clean work areas.

In the instrument cleaning /sterilisation area allow sufficient bench space for the flow of instruments and equipment from dirty to clean.

Work surfaces

Work surfaces include treatment trolleys, treatment couches, operator's stools, debris trays, floors and instrument decontamination and packaging areas.

Work surfaces should be:

- non porous / impervious ;
- smooth / seam or join free; and
- easy to clean.

Suitable work surfaces include vinyl, stainless steel, laminates and reinforced glass.

Unsuitable work surfaces include wooden and painted surfaces, textured or moisture retaining surfaces.

Floor surfaces

Carpet must not be used in clinical areas and all flooring should be in good condition and easy to clean. Non slip surfaces are recommended

In premises where there is no alternative to carpeted floors, the use of a hard wearing durable plastic carpet protector of at least 1.5 metre square, such as those available from an office supplier may be used beneath the foot rest of a podiatry treatment chair until refurbishment. This alternative is only suitable as a temporary measure until a vinyl floor is installed.

Hospital grade vinyl floors are recommended for clinical areas. Regardless of choice however, all clinical areas (including equipment processing areas) should have smooth, non porous floor covers which are easily cleaned.

Carpet should be limited to waiting room and administrative areas.

Hand washing basins

Sinks for the purposes of hand washing should:

- be readily accessible in the clinical area;
- be dedicated for the purposes of hand washing not for other cleaning functions ;
- have elbow control or non-touch taps;
- run hot and cold water; and
- be accompanied by liquid hand wash (see hand washing for details) and disposable paper or single use clean cloth hand towels.

Fixtures and fittings

Any fixtures and fittings in the podiatry clinic should be easy to access and clean. Blinds which avoid the accumulation of dust and are easy to clean are preferred over curtains.

2.4. Clinical work practices

(Refer also to: Clinic layout and workflow)

Salient points

- **developing good work practises significantly reduces the risk of contamination and therefore infection ;**
- **preplanning of the infection control strategies to be undertaken is recommended prior to the treatment and should become routine ;**
- **patient skin preparation aims to keep microorganisms below a level which may result in clinical infection;**
- **any item that comes into and out of the treatment field must be sterilised, cleaned or discarded between each patient;**
- **instruments or equipment intended for single use and/or labelled as 'single-use' by the manufacturer must be disposed of after use; and**
- **the use of creams or medicaments must be carefully approached to avoid contamination and cross infection.**

Patient skin preparation

Prior to any podiatry treatment that entails debridement or penetration of skin or nails, the skin surface should be clean and may require the application of a skin disinfectant. This aims to keep microorganisms below a level which may result in clinical infection.

Skin preparation may be as simple as a premoistened towellette or as prescribed as a surgical preparation.

Individual sachets and single patient use items are preferred.

The following preparation may be used as skin disinfectants:

- 70%-80% w/w ethyl alcohol;
- 60%-70% v/v isopropyl alcohol;
- alcoholic chlorhexidine 0.5% to 1% w/v: (Using 60-70% isopropanol or ethanol);
- aqueous chlorhexidine 0.5 to 4% w/v,
- aqueous or alcoholic povidone-iodine 10% w/v (1% available iodine); and
- 1% w/v diphenyl ether (Triclosan).

All skin antiseptics and disinfectants are regulated by the Therapeutic Goods Administration (TGA) and are either registered medicines or listed medicines. A number issued by TGA is required to be displayed on the label (AUST R or AUST L number).

The product label claims and the manufacturer's instructions for use should always be strictly followed. Used by dates must be observed.

Spraying of skin disinfectants is not advised as inhaling aerosol product may have adverse effects.

Surgical skin preparation should be with a TGA approved product.

The product should be applied to clean skin following the manufacturer's instruction. Antisepsis of the area is achieved when coverage of product is complete.

The product should be allowed to dry or left for the stated times after application prior to commencement of the procedure.

Single use items are preferred. If not available, the following recommendations are made regarding the use of bulk containers of skin disinfectant:

- containers should be labeled with the date of opening and discarded after a month; or by the use-by date stated on the bottle, whichever comes first;
- before each treatment sufficient skin disinfectant should be placed into a small; container. This container should be sterile for a surgical procedure; and
- at the end of the treatment, any decanted fluid remaining must be discarded and a new container and fresh skin disinfectant provided for the next patient.

Cleaning and maintenance of the treatment field

Podiatrists and podiatry assistants must be aware of situations where cross contamination of products may occur during routine and sterile surgical procedures.

Protocols to prevent cross-contamination of multiple-patient use products must be developed.

These should include:

- establishing a separate area designated for the placement of bulk medicaments and dressings away from treatment field;
- have only the current patient's requirements in the immediate working environment; and
- developing protocols for cleaning the treatment field between each patient:
 - include role of operator and podiatry assistant;
 - protocol if working without an assistant; and
 - prior identification of appropriate personal protective equipment, hand washing and precautions to be used.

The treatment field is to be cleaned between each patient.

Table two: Cleaning the treatment field between patients

Waste	Sharps General	-Remove and discard sharps at point of use -Separate and discard
Instruments	Remove gross soiling by dry wiping Place in used instrument tray or dedicated rigid walled container for transport to cleaning area	
Treatment Field	Wipe down Clean	-Patient chair -Treatment trolley / cabinet -Nail drill handpiece and cable -Debris tray -Floor surfaces

Treatment field

The treatment field encompasses the:

- patient's lower legs and feet;
- treatment surface eg. Examination couch or bed (in domiciliary settings);
- examination light;
- nail drill handpieces and cables;
- debris tray (if used); and
- treatment trolley.

Any item that comes into and out of the treatment field must be sterilised, cleaned or discarded between each patient.

Developing good work practises significantly reduces the risk of contamination and therefore infection.

To limit the surfaces that are contaminated avoid placing footwear, orthoses and case records on benches and treatment trolleys that are used as part of the treatment field.

If items are placed in this area it should be cleaned prior to being set up again as part of the treatment field.

Preplanning

Preplanning of the treatment to be undertaken must occur and should become routine.

Treatment planning will include:

- sourcing all instruments and blades to be used during the treatment ;
- pre-dispensing any solutions, and topical medications;
- preparation or pre-cutting of materials, dressings and cotton probes/balls;
- pre-positioning the light, chair and clinical treatment surface; and
- presetting nail drills and /or dust extracting suction.

Treatment fringe

The treatment fringe is the area outside the treatment field where bulk dressings, medications, solutions, local anaesthetic and equipment are placed. Contamination can occur if surface contact and transfer of articles from the treatment fringe to the treatment field occurs without using aseptic techniques.

This may require the operator un-gloving to access an article before hand decontamination and re-gloving.

Accessing of additional instruments and materials

Retrieval of additional instruments and materials from outside the treatment field is often inevitable.

Drawers must be opened by un-gloving and washing or cleansing hands or by adopting a suitable no touch technique such as the use of transfer tweezers.

The drawer is closed with the forearm and kept closed to protect contents against contamination by aerosol, dust or debris.

In these circumstances either:

- remove gloves and wash hands or use an alcohol gel hand rub;
- use transfer tweezers to retrieve items from cupboards and drawers ;
- transfer tweezers should be in a separate container from other instruments;
- pick up transfer tweezers by a gloved hand or a clean, ungloved hand; and
- or call an assistant to 'hand on' the items.

Treatment debris

Debris trays

- debris trays are a potential source of cross contamination;
- they should be emptied and thoroughly cleaned between each patient; and
- not all treatment debris may be collected in the trays and may be on the floor.

Floors

Floors surfaces must be vinyl or other similar easy to clean surface and should be swept or vacuumed in between each patient.

Vacuum cleaners must be regularly emptied.

Small rechargeable vacuums have smaller collection bags and require:

- a schedule for emptying, based on usage;
- empty bags before $\frac{3}{4}$ full or when indicated by the equipment to avoid spillage;
- an overfull collection bag will result in poor suction and may result in the spread of dust and debris; and
- maintenance and cleaning of the whole unit should follow the manufacturer's guidelines.

Single use items

Instruments or equipment intended for single use and/or labelled as 'single-use' by the manufacturer must be disposed of after use.

Any item that cannot be adequately cleaned and sterilised will be single use.

Reprocessing of any item marked single use, or designated as single use, would require rigorous assessment of the reprocessing system.

The reprocessing of single use items has been designated a manufacturing activity and under the regulating control of the Therapeutic Goods Administration (TGA). This means that a facility planning to reprocess a single use item must be approved by the TGA regulatory body as a reprocessing facility.

Application of creams and medicaments

If moisturising, emollient or medicated creams and other medicaments are to be used they should be accessed with clean hands or clean gloved hands. At the end of a treatment, after all used materials, dressing instruments and sharps have been discarded, the cream / medicament can be applied.

If dispensing from multi use pots or containers use a disposable wooden spatula or clean, metal spatula. For multi use of products in tubes extrude a small amount onto a tissue or gauze swab and discard, then dispense required amount.

Local anaesthetic

The Australian Drug Evaluation Committee [ADEC] advises that injectable products packaged in multidose vials are **NOT** acceptable.

Single patient use vials of local anaesthetic must be used.

The most effective way to avoid cross infection via injection of medication is through the use of:

- single use vials or ampoules and single use sterile injecting equipment; and
- single use prefilled syringes.

Regulations for storage and administration of medications must be followed.

Wound dressings

The application of wound dressings must be conducted following standard precautions utilising a 'clean' aseptic technique. Additional precautions may be required if indicated.

Wound dressings intended for single use and/or labelled as 'single-use' by the manufacturer must be disposed of after use. The use of single use dressings is preferred where possible.

Where a product is available in multi-use containers, the manufacturer's guidelines must be observed at all times. The product should be dispensed into a separate sterile container prior to use and any unwanted portions discarded immediately after the procedure.

Liquid nitrogen

Due to the multiple use nature of liquid nitrogen, strategies must be in place to prevent contamination occurring. Where a treatment is being conducted, a small amount of liquid nitrogen can be very carefully decanted for use and discarded once the treatment is complete.

Alternatively, if the liquid nitrogen ladle is to be used, fresh application sticks must be used each time the liquid nitrogen is dipped in and the left over portion discarded once the treatment is finished.

2.5. Waste disposal including sharps management

(Refer also to: Decontamination and cleaning of instruments; Risk management; and Work practices and procedures)

Salient points

- **adequate procedures for disposing of waste generated in podiatric practice, are important in reducing the potential for transmission of infection;**
- **waste disposal must comply with; respective state/ territory legislation, local regulations, and AS/NZS 3186: Management of clinical and related wastes and the National Guidelines for Waste Management in the Health Care Industry (NHMRC 1999b);**
- **identification of waste category and appropriate segregation should occur at the point of generation ;**
- **the facility that generates clinical waste is responsible for the safe pathway of that waste until disposal; and**
- **it is essential that all podiatrists are fully trained in the recommended techniques for the safe handling of sharps as inappropriate handling of sharps represents a major cause of incidents involving exposure to blood borne diseases.**

In developing procedures for waste disposal in the podiatric setting, attention must be paid to its safe; identification, packaging, labelling, storage, transport, treatment and disposal, from the point of generation to disposal. (CDNA, ICG, Part 3; 15-1) Identification of waste category and appropriate segregation should occur at the point of generation.

Categories and disposal of waste

Health industry wastes can be categorised as: clinical, related and general. (Refer to Table three) Waste suitable for recycling, such as cardboard, paper and plastic, should also be considered for environmental reasons.

Table three: Categories of health industry waste

Clinical waste includes:	Related waste includes:	General waste includes:
Discarded sharps Laboratory and associated waste directly associated with specimen processing Human tissues, including material or solutions containing free flowing blood; and Animal tissue or carcasses used in research	Cytotoxic waste Pharmaceutical waste Chemical waste Radioactive waste	Other wastes that do not fall into the above categories. It forms the bulk of waste generated by health care establishments and is of no more public health risk or concern than household waste

Waste should be identified and segregated by category, at its point of generation. Correct containment, transport and disposal of waste should then follow. AS/NZ 3816 provides protocols for this. The facility that generates clinical waste is responsible for the safe pathway of that waste until disposal. A current contract with a waste disposal contractor should be held including details of the type and site of disposal.

Table four outlines the recommended method of disposal based on the type of health industry waste.

Table four: Type of waste and method of disposal

Type	Method of Disposal
<p>1. Sharps: ie used needles and syringes, scalpel blades, razors and other contaminated sharp objects.</p>	<ul style="list-style-type: none"> • needles should never be re-capped, bent, broken or disconnected from syringes following use; • needles should be disposed of correctly into puncture proof sharps containers. Containers should conform with AS 4031 – (non reusable containers) or AS/NZ 4261 (reusable containers), eg. Click Smart; • containers should be sited approximately at a height between 1.1 and 1.3 metres to enable visualisation of the opening. Those sharps containers which prevent direct access to contents are not limited to height constraints; • containers should be fixed to trolleys and/or walls, or on mobile trolleys; • containers should <u>never</u> be placed directly on the floor to allow access by children; • sharps containers in use which prevent direct access to opening, eg, B&D ‘point of use’, Daniels “Sharpsafe” should be attached in each Procedure Room or where procedures are performed; • when 2/3 full containers should be sealed and removed to collection / disposal site; and sharps are disposed via approved state governing body method. <p>NB: If a valuable is accidentally lost in a sharps container, do not attempt to retrieve item. Seal container and identify. Contact management / Infection Control Coordinator.</p>
<p>2. Includes materials or solutions that contain free flowing or expressible blood. Urine and faeces included <u>only</u> if visibly blood contaminated.</p> <p>NB.*Sanitary waste</p>	<ul style="list-style-type: none"> • placed into yellow containers or bags displaying the international black biohazard symbol; • when full, bags / bins should be removed and transported to collection / disposal site; • clinical waste should be disposed via approved state governing body method; and • sanitary waste from hospitals is not deemed to be clinical, therefore can be disposed of via the general waste stream. <p>*NB: This can be subject to interpretation by local authorities – in such cases compliance with the relevant authority requirements is advised.</p>
<p>3. General Waste</p>	<ul style="list-style-type: none"> • all waste not falling into the aforementioned categories is disposed into plastic garbags; • when full, bags should be sealed and removed to general waste collection area; and • disposal is via landfill.

(Source: The Podiatrists Registration Board of Victoria Infection Control Manual, 2004, Section 7-1, Table 1)

Sharps management

It is essential that all podiatrists are fully trained in the recommended techniques for the safe handling of sharps. Inappropriate handling of sharps represents a major cause of incidents involving exposure to blood borne diseases.

Standard Precautions should apply when handling sharps.

Methods of handling sharps should be devised to minimise the risk of injury:

- sharp instruments and equipment should not be passed by hand between podiatry workers;
- needles should not be re-sheathed, bent, broken or removed from disposable syringes by hand;
- separation of needle from the disposable syringe using the sharps container de-notching mechanism is recommended; and
- the podiatrist who has used the sharp instrument or equipment must be responsible for its immediate safe disposal following use.

This must be at point-of-use wherever possible

- sharps waste should be segregated from general waste at the point of generation;
- sharps containers should be placed so that children and other unauthorised persons cannot reach them under any circumstances; and
- sharps must be discarded in a clearly labelled, puncture proof container that conforms with AS 4031 or AS/NZS 4261, as appropriate.

AS/NZS 3825 Procedures and devices for the removal and disposal of scalpel blades from scalpel handles specifies that an approved blade-removing device should be used to enable removal of the blade without manual handling.

All health care facilities should have written protocols for the safe handling of sharps and ensure adequate training is offered to any staff involved in the handling of sharps.

Further information:

For further information on Waste Disposal and Sharps Management, refer to;
CDNA, ICG, Part 3; 14 - Handling and Disposal of Sharps, Part 3; 15 - Management of Clinical and Related Waste, National Guidelines for Waste Management in the Health Care Industry (NHMRC 1999b) and AS 3825 (1998) Procedure and Devices for the removal and disposal of scalpel blades from scalpel handles.

Section 3. Reprocessing re-usable instruments and equipment

Salient points

- **the instruments and equipment used in podiatric practice must be reprocessed appropriately in consideration of the level of risk of transmission of infection;**
- **sterilisation is a term describing the use of a physical or chemical procedure to destroy all microbiological life, including bacterial spores;**
- **it is an essential process for any instrument or equipment which may penetrate skin or mucous membrane, come into contact with blood or body fluids, or be capable of cross infection;**
- **thorough cleaning prior to reprocessing is essential as if debris or residues are not removed they may prevent sterilisation;**
- **the most effective and reliable form of sterilisation of instruments and equipment is by steam under pressure (moist heat) and thus is the preferred method of sterilisation in office-based practice;**
- **disinfection does not make instruments sterile / equipment sterile and is therefore not a substitute for sterilisation; and**
- **AS/NZS 4187 and AS/NZS 4815, or an equivalent protocol, must be fully followed, including validation of sterilisation.**

In preventing cross infection, attention must be given to all potential sources of contamination with infectious agents. "The risk of transferring infections on instruments and equipment is related to the presence or absence and burden of infectious agents (number and virulence), the type of procedure (eg invasive versus non-invasive) and the body site where the instrument is used." (CDNA, ICG, Part 3; 4-9) The instruments and equipment used in podiatric practice must be reprocessed appropriately in consideration of the level of risk of transmission of infection. The procedures and processes for the cleaning and sterilisation of instruments is given in AS/NZS 4187 and AS/NZS 4815. For the safe and effective reprocessing of instruments and equipment it is essential that all steps described in these standards are adhered to fully.

Safe and effective processing of re-useable instruments involves:

- cleaning to remove organic and chemical residue as soon as is practicable, followed by;
- disinfection or sterilisation.

Level of processing required

The level of processing of re-useable instruments and equipment should be conducted according to their intended use; the site where the instrument will be used and the risk associated with a particular procedure. (CDNA, ICG, Part3; 16-3) The Spaulding classification system (Spaulding 1968) suggests that instruments can be classified as critical, semi critical and non critical. Table five outlines the level of processing that is required according to this classification system.

Table five : Level of processing required for instruments and equipment according to Spaulding Classification (This list is not exhaustive but serves to illustrate the principle by example)

Category	Application	Process	Example
Critical	Instruments and equipment which enter, or are capable of entering, tissue that would be sterile under normal circumstances or the vascular system.	Sterilisation	Podiatry instruments capable of penetrating the skin such as nail clippers, scalpels, files and burrs.
Semi-critical	Instruments and equipment which come into contact with non-sterile mucosa (or non-intact skin).	Sterilisation is preferred (High level disinfection at a minimum if other methods are not available or not suitable)	Instruments such as endoscopes etc, generally not related to podiatric functions.
Non-critical	Instruments and equipment which come into contact with intact skin.	Cleaning	Doppler probe, blood pressure cuffs, biothesiometer etc.

(Source: Adapted from New South Wales Health, Infection Control Policy, Pg 22
 Web site: http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_247.pdf)

3.1. Decontamination and cleaning of re-useable instruments and equipment

(Refer also to: Waste disposal ; Sharps management; and Clinical layout and workflow)

Cleaning and instrument decontamination is the first essential step for effective sterilisation and disinfection processes. If debris or residues are not removed they may prevent sterilisation and therefore adequate cleaning is of the utmost importance.

Instrument cleaning should be carried out in a double sink. If a double sink is unavailable then separate bowls must be used for rinsing and washing. Hand washing should be carried out in a dedicated hand-washing sink.

Water for cleaning should be of potable or drinkable quality.

Hard water may influence the amount and the action of cleaning products.

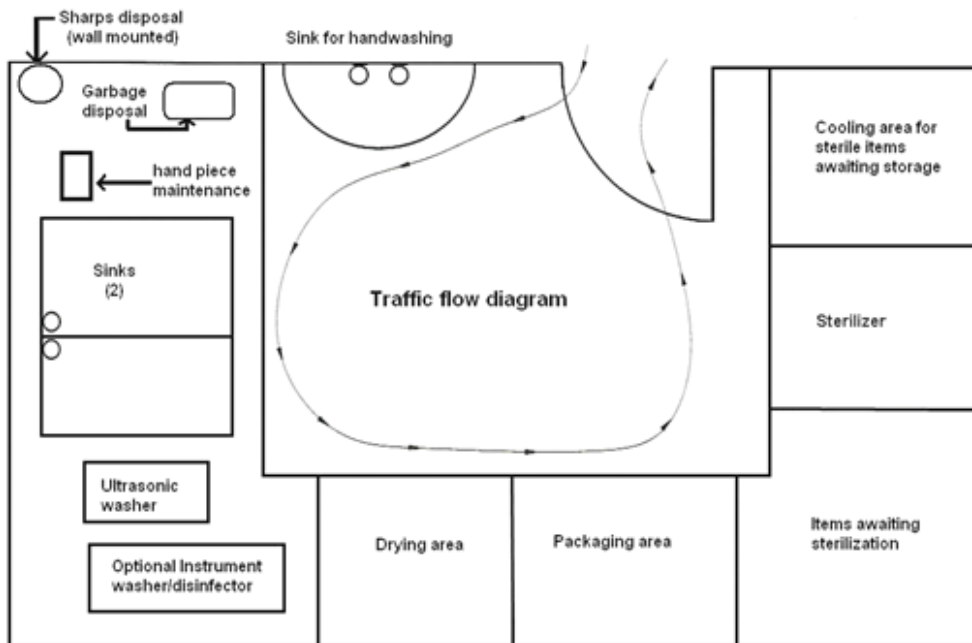
Water with high mineral content is not suitable for rinsing instruments as the mineral deposits can permanently damage instruments and shorten the life of instruments.

The instrument cleaning process can be broken down into the following steps:

- immediate handling after use;
- initial rinsing;
- manual or mechanical cleaning;
- final rinsing;
- drying; and
- inspection.

Standard precautions must be followed during instrument cleaning including the use of personal protective equipment. The cleaning area must be dedicated for that purpose only. Figure two presents a suggested layout for a reprocessing area and workflow.

Figure two: Suggested layout for a reprocessing area



Notes:

Arrow direction indicates the flow of instruments and equipment from dirty – clean – sterile.

Personnel working in the processing area should wash their hands:

- *after handling soiled items and removal of gloves;*
- *before handling clean items; and*
- *before handling sterile items.*

(Source: Reproduced from Lohead, L, Cleaning, Disinfection and Sterilisation. A guide for Office-Based Practice. (2004))

Step one. Immediate handling after use

It is good clinical practise to place waste into containers or a waste bag during the course of treatment.

This separation:

- makes subsequent cleaning easier; and
- prevents instrument deterioration.

Remove blades, burrs and discard used consumables at the point of use.

Remove gross debris from instruments at the point of use or as soon as possible as this reduces the likelihood of injury from sharps.

Dirty instruments should be placed in a dedicated rigid walled container for transport to the cleaning area.

Step two . Initial rinsing

Pre-rinse instruments in cool running water to remove gross soil. This should be conducted as soon as possible after use and instruments should not be allowed to dry before cleaning.

Step three. Cleaning: mechanical or manual

Cleaning is the essential first step in the effective sterilisation processes.

Mechanical cleaning is preferred as this:

- reduces the risk of sharps injuries; and
- maintains instruments in good condition.

Mechanical cleaning may be with an ultrasonic cleaner or instrument washer.

The instruments require gross soil rinsing prior to placing in an Ultrasonic Cleaner or Instrument washer. Ultrasonic Cleaners and instrument washers reduce the handling of soiled instruments.

Ultrasonic cleaners

These are used to clean reusable metal instruments and are particularly effective for hinged, jointed or serrated instruments.

They must be validated daily by way of a Foil Test or recognised soil removal test and the results recorded in a log. Ultrasonic cleaners must be filled with fresh solution daily or sooner if cloudy.

The detergent used in the ultrasonic cleaner must be documented and used as per the manufacturer's instructions.

Manufacturer's instructions should be followed wherever possible in the use of ultrasonic cleaners. For details on use and testing procedures of ultrasonic cleaners, refer to AS/NZ 4185.

Further information:

Ultrasonic cleaners must also comply with AS2773.2 and AS/NZS 4815. See these standards for further information.

Instrument washers

These are closed cabinets washers linked to a water supply and drainage.

The cycles should include pre-rinse and washing cycles and one or more hot rinses.

The manufacturer's instructions for cycle times, cleaning products and drying agents must be followed.

The cleaning agents and rinse additives products used in the instrument washers should be documented and used as per manufacturer's instructions.

The instrument washer should be regularly cleaned and maintained.

Manufacturer's instructions should be followed wherever possible in the use of instrument washers.

Further information:

For details refer to AS 2495, AS 3836 and AS/NZS 4815.

Manual cleaning

Cleaning equipment may include:

- small firm instrument brush with plastic bristles ;
- light grade nylon scouring pad;
- wire 'dental' bur brush;
- non linting drying cloths; and
- a dedicated sink or bowl designed for the purpose.

Cleaning equipment must be:

- non-abrasive;
- maintained in good condition;
- free from visible debris;
- cleaned, rinsed and stored dry; and
- used for instrument cleaning only.

The procedure for manual cleaning includes:

- the use of protective gear such as plastic aprons, gloves, and face / eye protection;
- instruments are disassembled where appropriate and immersed in warm water (not hot as this causes protein to coagulate making it difficult to remove) and a suitable detergent; and
- all visible soiling or debris is removed.

The choice, care and maintenance of cleaning equipment should be documented in the procedure manual.

Cleaning products

Generally products should be:

- biodegradable;
- liquid;
- non abrasive;
- low foaming;
- free rinsing; and
- mild alkaline formulation.

Staff must be trained in safe handling and use of all products.

Cleaning agents should be labelled in compliance with statutory regulations. Material Safety Data Sheets and Product Information should be available. Products should be supplied in manageable quantities and stored appropriately.

Household products **must not** be used for cleaning instruments due to their high foaming additives and the perfumes, dyes, and emollients that are difficult to rinse away and build up on instruments causing damage.

Step four. Final rinsing

Rinse instruments in hot running water to remove all residues. (Jointed instruments function better if rinsed in hot demineralised water.)

Step five . Drying

Dry instruments thoroughly with a lint free cloth:

- cloths should be dedicated for drying of instruments only;
- dry instruments immediately while still hot from rinsing; and
- residual water may impede sterilisation and damage instruments.

Items should not be dried in ambient air.

Step six. Inspection

Inspect instruments with the naked eye in strong light to ensure they are clean, free of residues and stains.

Check for function and condition of items and separate for repair or replacement if necessary.

Lubrication

Solid and hinged instruments should **not** be routinely lubricated or 'milked' following the cleaning process. Stiffness of hinged and spring type instruments, staining and rusting may be from:

- inadequate cleaning;
- inadequate drying prior to sterilisation; and
- frequent steam sterilisation without use of an effective drying cycle.

Lubrication will not overcome these process problems.

Use of mechanical cleaning equipment will improve function and instrument condition.

If used, lubricants must be water miscible and used following the manufacturer's instructions; the process should form part of a documented practice maintenance schedule.

Liquid lubricating 'milk' must be mixed as per manufacturer's instruction and discarded after each use.

3.2. Bagging and packaging of instruments and equipment

(Refer also to: Monitoring and validating the steriliser process; Storage of sterile items; Loading and drying; and Unloading of sterilisers. Also see Appendix 2 diagrams)

The practice of bagging and packaging of instruments is recommended to facilitate safe and effective sterilisation and maintenance of sterility during storage.

A practice must have enough instruments to allow sufficient time to decontaminate and process all instrument prior to use.

Combinations of packs including treatment instruments, gauze, cotton buds or balls, dressings, hollowware and area drapes need to undergo validation.

Chemical indicators may be used to verify to the end user that a tray has undergone successful sterilisation. A class 4, 5 or 6 chemical indicator appropriate for the steriliser is recommended for use but must be used if no printer is attached and may also be included in large packs. A class 1 chemical indicator should be included in laminate pouches which do not have an external chemical indicator.

Instrument pack sizes should be validated.

Packaging and wrapping prior to steam sterilisation

Packaging and wrapping materials must comply with A.S 3789.2 and AS 1079.2

Packaging and wrapping materials should allow air removal and steam penetration of the pack.

All material used for packing or wrapping must be tested to establish the penetration and drying times (pouches and bags = 0 penetration time).

Instruments with hinges and ratchets must remain open and unlocked.

All sharp pointed instruments should be protected to stop penetration of the pouch during the sterilisation, transportation, handling and storage of the instruments.

Trays for instrument sets should be perforated to allow penetration of steam and facilitate drying of pack.

To prevent damage dissimilar metals e.g. the tray and loose instruments should be separated.

A layer of a single use, non-linting sterilisable product may be used to separate metals during sterilisation.

Disposable wraps are recommended for use according to AS 1079. Linen wraps are not recommended.

Single use wraps must be disposed of after use.

Laminated pouches

When using preformed laminates pouches:

- select size of pouch to allow effective sterilisation of instruments – items should not over stretch or distort the pouch or contact the edges of pouch;
- when sealed there should be approximately 2cms of empty pouch around the item;
- sharp instruments may perforate laminate or paper and should be protected to prevent perforation but allow exposure to sterilising agent;
- single instruments pouches should be placed in a 'toast rack' for effective sterilisation; and
- multiple instruments in a laminate pouch may entrap condensate if placed in 'toast rack' or over filled
- effective sterilisation may only be achieved by laying pouch flat on steriliser tray [paper side down]; and
- position pouches to allow egress of air and condensate and ingress of sterilising agent.

Hollowware

- Hollowware items such as stainless steel bowls may entrap condensate and should be packed with opening to the paper side and adequately spaced;
- when placed on steriliser tray, place hollowware so that all openings face the same direction and that the contents can not move inside the pack; and
- place hollowware tilted on its side in downward displacement sterilisers or upside down in pre-vacuum sterilisers.

Packaging and wrapping prior to dry heat sterilisation

Packaging or wrapping materials for processing in items in a dry heat steriliser may be:

- paper bags and paper wrapping materials [may become brittle];
- nylon [non-porous, non-cellulose based] wraps ;
- sealed metal or glass containers; and
- aluminium foil.

Sealing

The purpose of sealing is to maintain pack integrity.

Sterilising bags and laminated pouches must be completely sealed.

The use of a heat-sealing machine is preferred.

Following sealing the seal must be checked to ensure it is complete.

Self sealing pouches and bags

There is currently no Australian standard or guideline for self-seal laminate pouches and bags.

Self-sealing laminate pouches or bags should be selected with attention to the effectiveness of the seal.

Self-sealing bags must be closed in accordance with the manufacturer's direction i.e. folded along the perforated edge of the flap to form a complete seal.

The seal should be checked before sterilising and after processing.

Gaps or ineffective sealing of laminate pouches may lead to leakage of the adhesive that could inhibit sterility, and damage instruments and/or contaminate the steriliser water.

Heat sealers

Steriliser bags and laminate pouches should be sealed with suitable heat-sealing equipment.

Heat sealing is the preferred method for sealing all steriliser bags and laminate pouches.

Checks of the seal must be made to ensure a complete seal.

Further information:

See appendix E of AS 4815: 2001 or appendix F of AS 4187: 2003 for more information on the selection and use of sealing equipment.

Refer to Appendix 2 of this document for diagrams illustrating envelope fold wrapping technique and sealing bags with steriliser indicator tape.

Indicator tape

Select tape specific to the mode of sterilisation. i.e. Dry heat indicator tape or steam indicator tape:

- the selected tape should change markedly demonstrating exposure to the relevant sterilising agent;
- the tape adhesive should be pressure-sensitive, non-toxic and adhere to clean surfaces;
- the tape should be compatible with the packaging material; and
- the tape shall have manufacturers name, batch number and date of production marked on the core.

When tape is used to seal a bag or pouches the open edge should be folded two or three times prior to taping the entire free edge with a continuous piece of indicator tape.

Tape should continue to the back of the bag on both sides to complete the seal.

Autoclave tape identifies contact with the sterilisation process however it is not a direct measure of sterility. In the event that the expected change in tape after sterilisation is incomplete the contents of that load must be removed and the reason explored.

Labelling packs and bags

Packs or trays of surgical [Critical] items should be labeled to link the steriliser cycle to the patient.

Label should include:

- batch number - Cycle or load number if more than one load processed in a day;
- pack contents;
- identification code or number to identify the sterilizer; and
- date of sterilization.

Labeling should be with:

- prepared [sterilisation] labeling systems;
- non-permanent marker pens; and
- the writing placed on paper if the pen is solvent based as it does not stick to plastic.

3.3. Sterilisers: types and usage

(Refer also to: Monitoring and validating the sterilisation process; Quality management - Off-site sterilisation services; and Steriliser cleaning and maintenance)

Sterilisation is a term describing the use of a physical or chemical procedure to destroy all microbiological life, including bacterial spores. It is an essential process for any instrument or equipment which may penetrate skin or mucous membrane, come into contact with blood or body fluids, or be capable of cross infection. The most effective and reliable form of sterilisation of instruments and equipment is by steam under pressure (moist heat) and thus is the preferred method of sterilisation in office-based practice. "In steam sterilisation, the combination of heat and moisture, maintained at a pre-set temperature-pressure-time relationship, coagulates cell protein, efficiently killing microorganisms." (AS/NZS 4815:2001 Pg 29) This technique includes a drying cycle where the packaged sterile instruments are dried before the steriliser door is opened. Steam sterilisation is the most widely used approach for sterilising instruments and equipment for use on critical and semi-critical sites, where the items are able to withstand moist heat.

Information on steam sterilisers is presented below, AS/NZS 4187 provides information on various other forms of sterilisation.

Steam sterilisers

There are a number of types of steam sterilisers (formerly called autoclaves) available.

The differences relate to the capability of the cycles of the steriliser in relation to removal of air from the chamber and the load prior to steam entry.

Three types of portable steam sterilisers appropriate for use in office-based environments are described below.

Each type has differing requirements related to monitoring and validation of the sterilisation process.

- AS/NZS 4815, AS/NZS 4187 and AS 2182 Standards apply.

Some recently released sterilisers have a choice of cycles for selection dependent on the load to be processed eg. Type N for unwrapped loads or Type B is for hollow instruments in pre-vacuum steriliser.

Sterilisers, steam, basic bench top

Suitable for the processing of non wrapped solid items.

Air removal from the load is by passive displacement, i.e. Steam pushing the air down and out through the drain in the base of the chamber.

Correct packing of the steriliser is crucial to facilitate the movement of the air from the unit and the entry of the steam.

The steam must be able to come in contact with all surfaces of the items loaded into the steriliser:

- the holding time for the cycle will depend on the type of the items loaded, and must be determined by a steriliser technician during the calibration and validation procedures for this steriliser;
- if fitted a heating element may assist in the drying of the load; and
- the drying process must be achieved with the steriliser door closed.

Steriliser, steam, assisted air removal bench top

Designed for the sterilisation of specified loads including non-wrapped solid products. Air removal may be by displacement as described above but assisted by pulses of steam or the unit may be designed to effectively sterilise specific loads.

The units may not fit the design characteristics of either an N type or B type steriliser; however the manufacturer must be able to demonstrate that particular loads or instrument types are sterilised by the use of specific challenge devices.

Sterilisers, steam, pre vacuum, bench top

This type of steriliser is capable of sterilising all wrapped or non-wrapped, solid, hollow and porous products.

Air removal utilises one or more strong vacuum stages together with positive pulses of steam. The effect of this is that air removal is more effective and rapid and this reduces the cycle time. Drying of the load is also assisted by a vacuum, which improves the efficiency of the drying process.

These sterilisers are suitable for wrapped and unwrapped cycles, and are the most efficient sterilisers as cycle times are much shorter than the downward displacement sterilisers. These units use a non-recycled water system to generate the steam.

Specific testing and monitoring requirements apply to this type of steriliser.

Water quality for steam generation

Generally good quality distilled water prepared for use in bench top sterilisers should be used in units to generate the steam this applies whether the unit recycles the water or dumps the used water after each cycle.

The quality of the distilled water is crucial to the life and function of the unit and it is recommended that the advice offered in appendix C of AS 2182 be followed.

Dry heat sterilisers

Dry heat sterilisers should comply with AS 2487.

Dry Heat is a simple sterilising process involving heating the chamber the air in the chamber and the load and holding that temperature at a high temperature for a long time.

These types of sterilisers are electrically heated and fan forced to reach temperatures of 160 – 180 Centigrade for a minimum holding time of 120 minutes plus penetration time.

Loading sterilisers

For steam sterilisation

Correct loading of sterilisers is essential for successful sterilising for several reasons:

- efficient air removal from the chamber and the load will permit total steam penetration and saturation, and allow proper drainage of condensate; and
- correct loading will reduce damage to packs and their content and maximise efficient use of the steriliser.

Some items are prone to entrap air and moisture in downward displacement type sterilisers. eg. Hollowware – non-perforated trays, metal bowls and jugs. These items must be tilted on edge to allow steam to contact all surfaces of the item and to enable the condensate to drain. Items may be upside down in vacuum extraction type sterilisers.

Sterilisers should be used in strict adherence to the manufacturer's instructions.

Correct loading patterns

A loading pattern diagram (appropriate to the steriliser) should be developed and tested as part of the calibration and validation process.

This pattern should be documented and kept with the steriliser.

Correct loading patterns include:

- loading items within the boundaries of the tray so that they do not touch the chamber walls, or fall off when the tray is in transit;
- a single layer of sterilisable, single use, non-linting towel may be used as a separating layer for dissimilar metals. This layer may prevent discolouration and damage during sterilisation;
- items packed in flexible packing material shall be loaded on edge with paper to laminate, or flat with the paper surface downwards;
- load trays loosely; and
- do not load beyond the capacity of the steriliser.

For dry heat

Prior to loading, the chamber may be preheated.

Place items evenly through out the chamber, spaced to allow air circulation and well clear of chamber walls.

Drying and unloading sterilisers

Use heat protection gloves or tray lifting lever and allow cooling before handling with bare hands.

On completion of the cycle the load should be removed from the steriliser and inspected for dryness. The sterilising indicators must be checked to see that they have changed appropriately (Refer to Monitoring and validating the steriliser process) and the integrity of the packaging before the instruments are released for use or storage.

Packed items that are not dry are not sterile and must be repacked and reprocessed.

If there is any indication of failure to sterilise then the entire load is not sterile, and cannot be released for use or storage:

- all items must be repacked and reprocessed;
- follow the documented practice policies and procedures to recall loads whenever there is evidence of a sterilisation failure; and
- the procedure should include a manner of recording the action taken and means of preventing a reoccurrence of the incident.

If the reason for the failure cannot be established, arrange for a technician to check the steriliser before commencing another load.

Instruments may corrode if stored moist and jointed instruments may become stiff and difficult to operate.

Packed and bagged items shall not be processed in a steriliser without a drying cycle as contamination of the packs occurs as soon as the door is opened and items are exposed to the ambient air.

WARNING – Sterilisers that do not have a drying cycle are only appropriate for use with unwrapped items.

Where items are required to be sterile at point of use and are processed in a unit without a drying cycle, these must be used immediately after processing to avoid the danger of contamination.

The process of unloading and transfer of these items must be documented in a procedure manual and a chemical indicator is recommended to be included with every load.

Cooling

Sterilised items shall be allowed to cool prior to storage:

- cooling items shall be put in a designated area away from other activities;
- cooling items shall not be placed on metal surfaces as condensation may result; and
- do not 'force cool' items by placing near air-conditioning vents or fans.

Monitoring and validating the steriliser process

(Refer also to: Cleaning and maintenance of sterilisers; Cleaning of the clinic; and Appendix 1 Summary of monitoring and validation)

Validation is the procedure for obtaining, recording and interpreting the results required to establish that the sterilisation process provides a consistent product that complies with preset criteria.

At present the following tests must be considered:

- Class 1 Chemical indicator;
- Class 4, 5 or 6 Chemical Indicator Testing;
- biological Indicator Testing;
- calibration by a service technician; and
- penetration time tests by a service technician.

AS/NZS 4815 is currently being updated. The following tests may also need to be considered upon its introduction:

- process challenge devices;
- Bowie dick test; and
- Class 3 chemical indicator test (dry heat only).

All steps of the process should be documented in the practice procedure manual. A steriliser logbook must be kept and daily and routine monitoring recorded.

Class 1 chemical indicator – process indicator

A Class 1 chemical indicator is a process indicator. It only demonstrates that the pack has been exposed to the sterilisation process and is there to readily distinguish processed from unprocessed items. It does not indicate that the pack contents are sterilised.

A Class 1 indicator **must** be used on each pack.

Class I indicators for Moist Heat may include:

- the arrows or dot markings on laminated or preformed pouches;
- the markings on the peel-off strip on the adhesive of a laminate pouch; and
- the markings or stripes that change colour on steriliser tape.

Class 1 indicators for Dry Heat may include:

- dry heat steriliser indicator tape; and
- dry heat "dots "

Class 4, 5 or 6 chemical indicator testing

Class 4, 5 or 6 Chemical Indicators demonstrate that the Steriliser load has reached sufficient temperature for a given period of time (*time at temperature*). This must occur for sterilisation to be achieved.

A Class 4, 5 or 6 chemical indicator **must** be used:

- in every load if the steriliser does not have a printer. However, it is considered best practise to use one in every load, even if the steriliser has a printer; and
- in every surgical pack in the least accessible area [for steam penetration] of the pack.

For Moist Heat: use a Class 4, 5 or 6 indicator. Check with the steriliser manufacturer which one is best suited to your steriliser

For Dry Heat: At present there are limited indicators for use with dry heat. The “Browne steriliser control tubes” which were initially rated class 4 and have now been upgraded to class 6 may be used. Check with your supplier that the indicator supplied is suitable for use in dry heat.

(A Class 6 Indicator is also known as an *Emulating Indicator* or cycle verification indicator.)

Biological indicator testing

Biological indicators measure the microbial killing power of the sterilising process and contain live spores which must be killed by the sterilisation process. (The biological indicators for some moist heat sterilisers may contain enzymes instead of live spores. Check with your steriliser manufacturer if unsure which to use in your steriliser)

The Biological indicator for moist heat is *Bacillus stearothermophilus*.
The Biological indicator for dry heat is *Bacillus subtilis*.

Biological Indicator Testing **must** be performed:

- annually at validation;
- at installation / commissioning of a new steriliser;
- following any major repairs to the steriliser; and
- following any changes to your challenge pack that would make it more difficult to sterilise or if the load size in the steriliser exceeds previously validated parameters

The process:

1. Biological Indicators are placed:
 - in the coldest part of the steriliser chamber (as identified by the service technician);
 - inside the densest part of your challenge pack (see penetration time test for further information on challenge packs); and
 - outside the steriliser (the control).
2. Three consecutive cycles are run using new biological indicators in each cycle. (The biological indicators must come from the same batch.) The same ‘control’ can be used each time so that a total of 7 biological indicators are required.
3. Once processed the indicators are cultured according to the manufacturer’s guidelines. This may be done in-house or through a pathology laboratory. Once incubated, all the indicators (except the control) must show no growth.

The results must be documented and kept as part of the Validation report.

All failures must be investigated and documented. Once the reason for failure has been determined the whole procedure must be repeated.

The role of the steriliser technician

A skilled person (steriliser technician) should undertake a preventative maintenance program at least annually in compliance with AS/NZS 4815:

- filters and door seals require checking, cleaning or changing twelve monthly, depending on the manufacturer's instructions; and
- the program should be specific for the unit and involve routine calibration of measuring devices, gauges, timers etc.

National Association of Testing Authorities (NATA) should certify the equipment used by the technician to calibrate and validate the steriliser annually.

Calibration of the steriliser (by a service technician)

This process is the routine checking and maintenance of the steriliser's measuring devices including the timers, gauges and displays. It is carried out by a **skilled service technician** using NATA accredited measuring equipment.

It must be undertaken:

- at commissioning of a new steriliser;
- at least annually (The service technician will advise you how frequently it is required for your particular steriliser – usually every 6 to 12 months); and
- following major repairs or maintenance.

Penetration time test (by a service technician)

This is performed by a **skilled service technician**.

The results of the penetration time test are used to determine the load time for the steriliser and must be documented. Thermocouple probes are inserted into the densest part of your **challenge pack*** and the time is measured that is required for the load and challenge pack to reach the required temperature. This procedure must be performed using a challenge pack and the most challenging load that would be processed in your steriliser.

A penetration time test is performed once only.

*A challenge pack is **your** most difficult to sterilise pack. It may as simple as a 'routine treatment' pack or as complex as a 'surgical' pack. It will vary depending on the practise site. Commercial challenge packs are available.

3.4. Monitoring steriliser efficacy

Documentation

Documentation establishes accountability and enables identification of sterility problems or failure.

The steriliser logbook, service manual and instruction manual must be kept with each steriliser.

Documentation must be kept of all:

- Service Technician Reports;
- Biological Indicator Testing;
- Sterilising Cycle Records;
- Batch Control Numbers; and
- Class 4, 5 or 6 Chemical Indicator Testing.

Sterilising cycle records

For each sterilising cycle the following records must be maintained:

- date of the cycle;
- steriliser number (if you have more than one steriliser)
- cycle or load number;
- exposure time and temperature (via permanent potentiometer or thermocouple);
- name or ID of person authorising the release of the load;
- specific load content eg wrapped instruments, surgical bundle; and
- readout results of the physical, chemical or biological indicators used.

Batch control numbers

Every load sterilised **must** be allocated a Batch Control Number .

The Batch Control Number must be recorded in the steriliser log book and include the following information:

- the date of processing;
- the number of the load for the day; and
- the number of the steriliser used (if more than one steriliser is used).

The Batch Control Number must:

- be labelled on every pack in the load; and
- be recorded on the case record of the patient on whom the instruments were used.

Recall protocol for sterilisation failure

A recall process may not be necessary if a validation process is in place as all loads are released based on the parameters established during validation.

In the event of sterilisation failure it is essential that a documented protocol be followed to ensure retrieval of items with questionable sterility.

Policies and procedures should be developed and documented in each practice.

Policy will address:

- what constitutes a sterilisation failure;
- the person with the responsibility to initiate the recall procedure;
- a manner of recording the action taken;

- this should include reason for recall;
- batch identification type;
- nature of items recalled including type and number;
- other persons or agencies contacted; and
- a means of preventing a reoccurrence of the incident.

Off-site sterilisation services

Some podiatry practices choose to use a commercial sterilisation service or rely on another practice, hospital or health care provider for their sterilisation needs.

When using an off-site sterilisation service, the podiatry practice must have evidence of the sterilisation services compliance with AS/NZS 4815 and AS/NZS 4187.

It is recommended that there is a clear and documented contract outlining:

- parameters of the service;
- who is responsible for decontamination, packing and preparation of instruments and equipment prior and after using an off site sterilisation service;
- process for safe transportation of instrument and equipment; and
- compliance with AS4815: 2001 for both the service and the podiatry practise in relation to the processing being undertaken by each party.

The podiatry practice should have documented procedures for decontamination packing and preparation of instruments and equipment prior to and after using an off site sterilisation service.

NOTE: There is some variation in State/Territory legal requirements for the owners of steam sterilisers. For example; in South Australia the steriliser must be registered annually with the Department of Administrative and Information Services. A certified inspector must inspect the Steriliser every 2 years (minimum) to the Australian Standard 3788.

Individual State/Territory legislative and regulatory requirements must be sourced by owners and podiatrists responsible for steam sterilisers to ensure compliance is adequately met.

3.5. Storage and transportation of sterile items

(Refer also to: Clinical layout and workflow, and Off-site sterilisation service)

All packaged and wrapped sterile items must be stored to ensure sterility is maintained.

Packaged and wrapped items must be:

- stored in an environment, which is cleaned regularly with detergent and water;
- protected from environmental contamination. i.e. in a covered container or designated drawer/cupboard;
- stored in order of sterilising date;
- stored away from sharp objects which might damage packaging; and
- a clear system of stock rotation must be maintained to ensure older stock is used before newer stock.

Shelf life of sterilised items

The life of a sterilised item is event-related, meaning that if the item has been adequately sterilised and stored then it remains sterile for use indefinitely.

For this reason expiry dates on sterilised items are no longer used. All sterile items must be inspected by the end user prior to use and any damaged packages of instruments must be opened and contents reprocessed.

Transport of instruments

Instruments may need transporting for home visits, visits to aged care facilities, or to other practises.

All pre-sterilised instruments and equipment should be transported in containers. Separate containers should be used for clean and dirty instruments.

Containers of a different colour for ready identification of clean and dirty are preferred.

The containers should be:

- secured with a lid;
- labelled 'Clean / Sterilised' instruments or "Used / Dirty" instruments;
- made of a rigid washable material eg plastic, stainless steel; and
- cleaned with detergent and water.

Section 4. Cleaning and maintenance of the podiatric clinic and equipment

(Refer also to: Standard precautions; and Personal protective equipment)

Salient points

- **efficient cleaning of the clinic, the sterilisers and other equipment minimises the risk of infection to patients and staff;**
- **cleaning must be performed on a regular basis in order to maintain a safe clean environment. Standard Precautions should be implemented when cleaning surfaces, equipment and facilities, including the wearing of personal protective equipment;**
- **a cleaning and maintenance program should be developed and documented in a Policy and Procedures Manual;**
- **records should be maintained of cleaning tasks and maintenance performed. This should include the date the task that was done and by whom; and**
- **condition of equipment should be noted during the cleaning process and any faults or defects reported.**

Detergents

Detergents for surface and environmental cleaning should be:

- biodegradable;
- low foaming;
- non-abrasive non-corrosive;
- non-toxic; and
- preferably liquid.

Alkaline detergent diluted with fresh tap water is recommended for all general cleaning. Follow the manufacturer's instructions for dilution. Water quality may effect dilution.

Disinfectants are not recommended for general cleaning. - Some disinfectants may fix protein, and thus create a physical barrier that can protect microorganisms.

The use of 'antibacterial' or disinfectant products for routine cleaning is not supported.

Spray type bottles may be used if the nozzle is adjusted to 'jet' not fine misty spray. Spray onto cloth not directly onto the surface.

Damp dusting is acceptable using a detergent and a clean cloth. Water may be luke warm but **not** hot.

Buckets are not recommended for use.

Cleaning of clinical areas and other facilities

(Refer also to: *Clinical layout and workflow; Waste disposal; and Sharps management*)

Table six: A suggested practice-cleaning program

	Treatment Room	Instrument Decontamination Area	Office Area	Waiting Area	Staff Area
Floors	Should be swept/vacuumed after each consultation	Daily	Weekly	Weekly	Weekly
Bench tops and horizontal surfaces	Daily	Daily	Weekly	Weekly	Weekly
General furniture and equipment	Daily	Daily	Weekly	Weekly	Weekly
Examination couch	After each use				
Trolley	Daily				
Nail drill dust bags	When ¾ full or as indicated by monitor				
Nail drill handpieces	After each use * Refer to <i>Nail drill cleaning and maintenance</i>				
Storage areas for sterile equipment	Weekly				
Ceilings, walls windows, doors	As required – when visibly soiled				
Air conditioner vents and fans	Monthly and as needed				
Air conditioner filters	As recommended by manufacturer				
Bins	Daily and as needed				
Sinks, hand basins and toilets	Daily and as needed				

Floors should be cleaned daily with a vacuum installed with a particulate-retaining filter, which is changed in accordance with manufacturer's guidelines. Brooms should not be used in patient / clinical areas as they disperse dust and bacteria into the air.

Cleaning of walls, blinds and curtains are generally not necessary unless they are visibly soiled, otherwise should be cleaned as necessary.

Walls must be kept in good condition and free of anything that will allow dust and moisture to accumulate which would allow the growth and multiplication of microorganisms.

Non-laminated notices should not be placed on surgery walls.

Notices and posters should not be attached with anything that will leave a residue or damage the surface when removed.

Cleaning of sterilisers

(Refer also to: Monitoring and validating the steriliser process)

Routine steriliser cleaning

Routine steriliser cleaning should follow the manufacturer's recommendations and involve:

- daily damp dusting of all external surfaces;
- the steriliser trays and loading rack cleaned at least weekly and if soiled;
- the chamber should be cleaned with a soft cloth or sponge, detergent and water;
- the chamber drain should be checked cleaned;
- the door seal/gasket should be checked and cleaned; and
- drainage of distilled water reservoirs and cleaning of reservoirs and pipework.

The steriliser cleaning should be documented as part of the regular practice-cleaning program.

Nail drill cleaning and maintenance

Electric handpieces used for drilling of nails should comply with Australian Standard 3200.1.0 and AS/NZS 4187. Handpieces must be cleaned after each use and wherever possible handpieces should be cleaned and sterilised after each use because the internal surfaces of high-speed hand pieces may be soiled with patient debris during use. Subsequent patients can then be exposed to infectious material if the debris is expelled. Cleaning of the internal and external surfaces of drills should be scheduled as part of a cleaning program. The manufacturer's recommendations for cleaning and maintenance must be adhered to.

Nail drill dust collection bags / burrs / sanding discs

Develop and adhere to a cleaning schedule based on usage:

- use appropriate personal protection when changing / cleaning nail dust collection bags;
- empty bags before $\frac{3}{4}$ full or when indicated by the equipment to avoid spillage. An overfull collection bag will result in poor suction and may result in the spread of dust and debris; and
- maintenance and cleaning of the whole unit should follow the manufacturer's guidelines.

Burrs

A pre-sterilised burr must be used for each patient:

- single use burrs must be discarded after use;
- reusable burrs must be cleaned well preferably in an ultrasonic cleaner or with a wire brush suitable for instrument cleaning; and
- reusable burrs must be inspected for cleanliness and condition before further processing.

Sanding discs

Sanding discs are single use and must be discarded between patients.

Orthotic manufacturing and adjustment areas

Areas used for orthotic manufacture and adjustment particularly on used orthoses, have the potential to disperse infected particles during the grinding process.

These areas should be located well away from the clinical area and instrument cleaning and sterilisation areas.

The area should be cleaned after each use and dust extraction maintained appropriately.

Section 5. Quality management

Salient points

- **each podiatric practice should have a strategic plan for infection control which is detailed in a practice procedures manual;**
- **the infection control procedures manual must include national minimum standards, State / Territory guidelines and State / Territory Podiatry Registration Board requirements; and**
- **a quality management program for the implementation and review of infection control strategies should be developed for every podiatric practice.**

5.1. Developing and maintaining a procedure manual

In order to implement a successful infection control program, each podiatric practice should have a strategic plan in place.

A comprehensive infection control procedures manual should be developed for each clinic which includes national minimum standards and relevant State / Territory guidelines. This manual should be reviewed at least on an annual basis and updated where necessary.

As a guide other inclusions to consider are:

- performance standards for routine work practices and procedures;
- strategies to monitor compliance with the infection control program;
- strategies to monitor the effectiveness of the infection control program;
- strategies to reduce the risk of occupational exposure of staff to infection;
- where appropriate, contingency plans to manage health care associated infections;
- a section dedicated to recording staff awareness including an area where all staff can sign and date to indicate that they understand the contents of the manual and agree to comply.

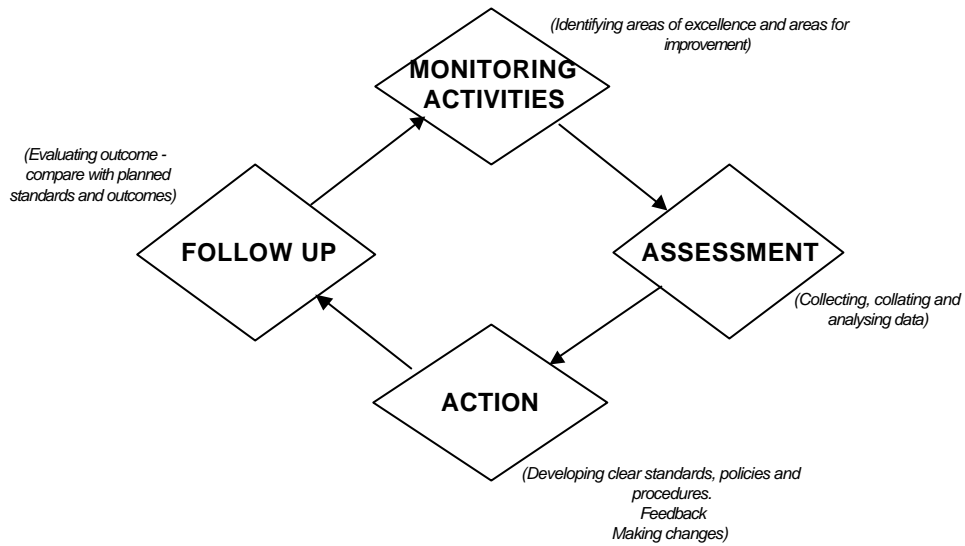
5.2. Monitoring quality


What is Quality Assurance?

Quality Assurance (Q.A.) is a planned and systematic approach to monitoring and assessing a service, which identifies opportunities for improvement and ensures that action is taken to make and maintain these improvements. Total Quality Management (T.Q.M.) refers to the philosophy which complements quality assurance. Prevention of problems, risk management, continuous improvement, team work and satisfying customers are the major themes. Each podiatric practice has a responsibility to; detail a quality assurance plan for infection control, ensure its timely implementation, and act on the outcomes of the program accordingly.

The quality assurance process tends to be “cyclic” in nature as changes made as a result of assessment and evaluation and their effects on service delivery must still be monitored. Thus quality assurance becomes an integrated part of the facility’s ongoing service provision. This process can be illustrated by The Quality Assurance Cycle (Refer to Figure three).

Figure three: The quality improvement cycle



 **Further information:**

For further information on quality management issues, refer to the CDNA, ICG, Part 2; 8 and AS/NZS 4815.

Section 6. Risk management

(Refer also to: Hand washing; Clinical layout and workflow; Personal protective equipment; Waste disposal; and Sharps management)

Salient points

- **standard precautions include immunisation against vaccine preventable diseases to ensure a high level of protection from infection for all health care workers;**
- **as part of the risk management process Podiatrists must monitor, investigate and act upon:**
 - **infection control breaches (eg sterilisation process failure, refer to section 3.3);**
 - **infectious exposures (eg blood and body fluid exposures) ; and**
 - **occupational Incidents (eg slips, falls, repetition strain injury).**
- **a process should be developed and documented to ensure a rapid response is initiated to breaches; and**
- **podiatrist and their staff should be trained and offered updates and education on a regular basis.**

Immunisations

Standard precautions include immunisation against vaccine preventable diseases to ensure a high level of protection from infection for all health care workers.

Podiatrist and their staff may be at risk of exposure to vaccine preventable diseases if they are involved in:

- close contact with patients, other staff and the general public;
- accidental injuries;
- assisting in surgical procedures;
- cleaning and packaging of instruments; and
- cleaning the clinic environment.

All podiatry workers should be aware of their immune status and keep a record of their immunization and infectious disease history. A personal immunisation record card should be maintained detailing all screening tests and vaccinations administered including; date, batch number, type / brand name of each vaccine.

Those podiatry workers who have not been immunized or naturally infected should have the following immunizations:

- Hepatitis B;
- Measles, Mumps, Rubella (MMR);
- Varicella (Chicken Pox);
- Tetanus; and
- Polio.

All podiatry workers should be offered annual ***influenza*** vaccinations. ***Hepatitis B*** - immunisation should be offered to all non-immune podiatry health care workers, particularly when there is a potential for exposure to blood and body fluids. Post immunisation screening should be done to establish immune levels.

Members of a surgical team should be Hepatitis B immunised

Hepatitis A - should be offered to podiatry workers who visit indigenous communities, home or long-term care facilities or establishments that care for intellectually impaired.

It is recommended that prior to commencing work podiatrists and their staff seek advice from a medical practitioner as to the appropriate immunisation.

Specific vaccination information may be obtained from the Department Human Services Immunisation Branch and the current Australian Immunisation Handbook contact details are detailed in the reference list and end of this document.

Health Care Worker Immunisation Record cards are available from Department of Human services Immunisation coordination Unit.

Routine assessment of disease and immune status

It is recommended that podiatrists and their surgical assistants know their infectious status for:

- Human Immunodeficiency Virus (HIV);
- Hepatitis B Virus (HBV); and
- Hepatitis C Virus (HCV).

Health care workers must not perform exposure-prone procedures if they are: human immunodeficiency virus antibody positive; hepatitis B e antigen positive and / or HBV DNA positive at high titres; or hepatitis C virus antibody positive and HCV RNA positive. (CDNA, ICG, Part 3; 24-1)

“Under current notification arrangements, medical practitioners must notify the chief medical officer or State / Territory health department of cases of HIV, HBV and HCV, by either name or code.” (CDNA, ICG, Part 3; 24-1)

All Health Care Workers should be aware that they have an obligation to care for the safety of others in the workplace, including fellow workers and patients under the Occupational Health, Safety and Welfare Act 1986 as well as under common law.

“A medical practitioner may be legally obliged to bring to the attention of the appropriate registration board any registered professional who is unable to practice competently or who poses a threat to public safety.” (CDNA, ICG, Part 3; 24-1)

Further information:

The Infection Control Guideline for the prevention of transmission of infectious diseases in the health care settings details further information on blood borne viruses and the health care worker. (CDNA, ICG, Part 3 ; 24).

Reduced immunity

Certain medical conditions can cause a reduced immunity to infection.

Workers should advise their employer if they are predisposed to infection so that they can be managed in a way to safeguard themselves, patients and co-workers.

Blood and body fluid exposures

Exposure to blood or body substances includes:

- needle stick injuries ;
- injuries from scalpels and other sharp instruments; and
- splashes to the mucosa (eye, nose, mouth) or broken skin.

In the event of an exposure, action should be taken immediately.

All podiatry practices should prepare a policy for the management of blood and body fluid exposures. All staff should be familiar with this policy – Appendix 3 of this document is a generic action plan for in the event of a blood or body fluid exposure. If unsure at any point a medical evaluation is recommended.

Further information:

The Infection Control Guideline for the prevention of transmission of infectious diseases in the health care settings details the appropriate actions to be taken in the event of an exposure (CDNA, ICG, Part 3 ; 23-1).

Management of blood and body fluid spills

Large blood and body fluid spills are unlikely in the general podiatry clinical areas however if a spill occurs don appropriate protective equipment – heavy-duty utility gloves are advised:

- clear area with dry, disposable towels;
- confine waste in a disposable waterproof bag;
- clean area thoroughly with detergent and water, rinse and dry area; and
- disinfection of the area is only necessary if bare skin will contact the area or it is a difficult to clean surface in the clinical area.

Disinfection of contaminated surfaces

Surfaces that cannot be cleaned (in carpet) adequately may need replacement.

For disinfection of blood or body fluid-soiled surfaces use a chlorine-generating disinfectant.

The bulk of the soiling should be removed and the area thoroughly cleaned with a detergent solution:

- the solutions should be left in contact with the surface for 10 minutes ;
- sodium hypochlorite solutions must be freshly prepared;
- sodium hypochlorite is irritating to skin therefore utility gloves must be worn;
- sodium hypochlorite may corrode metal and damage other surfaces ;
- liquid household bleach usually contains 4-5% available chlorine, diluted with tap water 1:100 gives 5000 ppm approximately and 1:1000 gives approximately 500 ppm; and
- materials used to absorb spillage should be placed in impermeable waste bags and disposed of appropriately.

Staff education

Podiatrists and their staff should be trained and offered updates and education on a regular basis.

Records of podiatrist and staff attendance at in-house and external training courses should be maintained.

This should include:

Basic infection control:

- standard precautions;
- personal protective equipment; and
- hand washing technique.

Sterilisation practices and procedure

- equipment cleaning and processing, disinfection and sterilisation.

Safe work practices:

- concept of working from clean to dirty; and
- scalpel blade removal.

Infection control issues specific to the practice such as:

- scrubbing technique; and
- gowning and gloving for surgical procedures.

The policies and safe work procedures developed by the practice to prevent injury or disease transmission

Each practice must develop an infection control manual and a policy and procedure manual.

Written work procedures and the practice policy manual are vital when inducting new employees or updating staff knowledge and competencies.

References

1. Australian Immunisation Handbook 8th Edition (NHMRC 2003)
2. Communicable Diseases Network Australia, Infection Control Guidelines for the prevention of transmission of infectious diseases in the health care setting doc. (January 2004)
Available on the Australian Government Department of Health and Ageing website:
<http://www.icg.health.gov.au>
3. Infection Control in Surgery published by the Royal College of Surgeons (RACS 1998)
4. Lohead, L, Cleaning, Disinfection and Sterilisation. A guide for OfficeBased Practice. (1998)
5. National Health and Medical Research Council (NHMRC) documents.
Re-use of single use items
6. National Guidelines for Waste Management in the Health Care Industry (NHMRC 1999b).
7. New South Wales Health – Infection Control Policy.
Web site: http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_247.pdf
8. Spaulding EH. Chemical Disinfection of Medical and Surgical Materials. (1968) In
Disinfection, Sterilisation and Preservation, Lawrence CA and Block SS (eds), Lea and
Febiger, Philadelphia, 517-531.
9. Therapeutic Goods Administration (TGA).
10. The Australian Confederation of Operating Room Nurses (ACORN) Standards Guidelines
and Policy Statements (May 2002 and updates) are recommended for those podiatrists who
are involved in operating room procedures.
11. The Podiatrists Registration Board of Victoria Infection Control Manual, July 2004. Healthcare
infection control management resources.
12. Queensland Health – Infection Control Guidelines.
Web site: http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_247.pdf

****Note: The following documents previously in existence were used in the development of these guidelines, in particular the Infection Control Policy and Procedures for Podiatrists, Podiatry Board of South Australia:***

- Infection Control Policy and Procedures for Podiatrists, Podiatry Board of South Australia, September 2004;
- Infection Control Guidelines, Podiatrists Registration Board of Tasmania, March 2000; and
- Infection Control Guidelines for Podiatry, Podiatrists Registration Board (Western Australia), 2002.

Australian standards of relevance

AS 1079.1 – 1079.5 (1993 – 1994)	Packaging of items (sterile) for patient care
AS 2182 (1998)	Sterilisers – Steam – Bench top
AS 2773 (1998)	Ultrasonic cleaners for Health Care facilities
AS/NZS 3200 (1998)	Medical electrical equipment - General requirements for safety
AS 4031 (1992) and Amendment 1 (1996)	Non-reusable containers for the collection of sharp medical items used in Health Care areas
AS 3825 (1998)	Procedure and Devices for the removal and disposal of scalpel blades from scalpel handles.
AS/NZS 4815 (2001)	[<i>currently being updated</i>] Office based health care facilities not involved in complex patient procedures and processes – Cleaning, disinfecting and sterilising reusable and surgical instruments and equipment
AS/NZS 4187 (2003)	Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in Health Care facilities
AS 4381 (1996) and Amendment 1 (1997)	Surgical face masks
AS/NZS 3816 (1998)	Management of Clinical and related wastes
AS 2487 (1981)	Dry heat sterilisers (hot air type)
AS/NZ 1337 (1992) & 1336 (1992 amended 1997)	Protective eyewear

Web sites of interest

Department of Human Services: - Communicable disease and Immunisation information
www.dhs.sa.gov.au

An audit tool on the Victorian Government Health Department web site to evaluate compliance with AS / NZ 4187 – 2003
<http://www.health.vic.gov.au/infcon/gramp/audit03.pdf>

Glossary of terms

Term	Explanation
Additional precautions	Precautions required when standard precautions may not be sufficient to prevent transmission of infection. These are used for patients known or suspected to be infected or colonised by highly transmissible pathogens that can be transmitted by airborne, droplet or contact transmission, or for those patients suspected of being infectious for Creutzfeldt-Jakob Disease (CJD). Additional precautions are designed to prevent transmission of infection by these agents and should be used in addition to <i>standard precautions</i> when transmission of infection might not be contained by using standard precautions alone.
Airborne transmission	Transmission by air of infectious agents from respiratory secretions. See also Droplet transmission
Antimicrobial	A chemical agent that, on application to living tissue or by systemic administration, will selectively kill or prevent growth of susceptible organisms. This definition includes antibacterials, antiprotozoals, antifungals, antiseptics and disinfectants
Antisepsis	The prevention of infection by topical application of bacteriostatic agents to tissues
Antiseptic	A substance that is recommended by its manufacturer for dermal application to kill microorganisms or to prevent the growth of microorganisms to a level that may cause clinical infection, and that is not represented to be suitable for internal use.
Asepsis	The prevention of microbial contamination of living tissues or sterile materials by removal, exclusion or destruction of microorganisms.
Aseptic technique	Is one which the instruments, the drapes and the gloved hands of the surgical team are sterile
Asymptomatic infection	Infection which does not display any clinical symptoms, but may still be capable of transmitting disease
Bioburden	The number and types of microorganisms present on surfaces to be sterilised.
Biological indicator	A preparation of standard bacterial spores on, or in, a carrier which is packaged in such a manner that the integrity of the inoculated carrier is maintained, and which is used to monitor a sterilising process.
Body substance	Includes any human bodily secretion, excluding sweat, or substance other than blood

Chemical indicator	Dye which can be impregnated into materials or contained within a device, and which changes colour when subjected to a sterilising process.
Challenge Pack	The most difficult pack that a practice sterilises used to perform the penetration test time.
Cleaning	The physical removal of foreign material, for example, dust, soil, organic material such as blood, secretions, excretions and microorganisms. Cleaning physically removes rather than inactivates microorganisms. Cleaning is accomplished with water, detergents and mechanical action. Cleaning must precede disinfection and sterilisation.
Clinical contact	All health care workers (HCWs) who have clinical contact with patients
Clinical Waste	Includes discarded sharps, laboratory and associated waste directly associated with specimen processing, human tissues, including material or solutions containing free-flowing blood, and animal tissue or carcasses used in research. See also Related waste, General waste
Contact Transmission	Transmission of infectious agents by person-to-person contact
Contamination	The introduction of microorganisms or foreign matter (or both) to sterile or nonsterile materials or living tissues [Reference: AS 4187]
Creutzfeldt-Jakob disease (CJD)	A progressive neurological disorder, one of the subacute TSEs caused by prions. Clinical features of CJD include a progressive cerebellar syndrome, including ataxia, abnormalities of gait and speech, and dementia
Critical site	Entry or penetrations into sterile tissue, cavity or bloodstream. The instruments used must be sterile.
Decontamination	The process of cleaning and or disinfecting to remove microorganisms or foreign matter (or both) from contaminated materials or living tissue
Disinfectant	A substance that is recommended by its manufacturer for application to an inanimate object to kill a range of microorganisms and that is not suitable for internal use
Disinfection	The inactivation of nonsporing microorganisms using either thermal (heat alone, or heat and water) or chemical means
Droplet transmission	Transmission of infectious agents in droplets from respiratory secretions. See also Airborne transmission.

Exposure-prone procedures	A subset of 'invasive procedures' characterised by the potential for direct contact between the skin (usually finger or thumb) of the health care worker (HCW) and sharp surgical instruments, needles or sharp tissues (spicules of bone or teeth) in both cavities or in poorly visualised or confined body sites (including the mouth). In the broader sense, and for the purpose of these guidelines, an exposure-prone procedure is considered to be any situation where there is a potentially high risk of transmission of blood borne disease from HCW to patient during medical or dental procedures.
General waste	Includes other wastes that do not fall into the categories of clinical or related wastes. This forms the bulk of waste generated by health care establishments and is not more of a public health risk than domestic or household waste. See also Clinical Waste.
Gravity displacement steam sterilisers	Steam sterilisers designed for general decontamination and sterilisations and instruments. They function by displacing air with steam, via a port in the bottom of the chamber. See also Porous load steam sterilisers
Health care associated infection	Infections that occur as a result of being in a health care establishment. See also Nosocomial infections.
Health care environment	Includes all environmental surfaces, including furnishings and fittings, and supplied services such as air and water. Other fixed services such as piped gases should also be considered part of the environment
Health care establishments	The various centres that are delivering health care services on a commercial or public health basis (eg hospitals, general practice, dentistry, community-based office practices, day-surgery centres, domiciliary nursing services, alternative health providers and other community services such as needle exchanges)
Health care setting	Refers to the setting within which health care is provided (eg acute care, long-term care, office practice, community care). See Health care establishments and Office practice
Health care workers	Refers to all health care professionals, including students and trainees, and employees of health care establishments who have contact with patients or with blood or body substances from patients
Holding time	For sterilisation by steam under pressure or by dry heat, the holding time is the minimum time for which the load must be held at the selected sterilising temperature
Iatrogenic infections	Infections that are acquired as a result of healthcare intervention.

Immunocompromised patients	People whose immune system is not functioning normally because of an immunodeficiency disorder or other disease, or as the result of the administration of immunosuppressive drugs or radiation
Invasive procedure	Any procedure that pierces skin or mucus membrane or enters a body cavity or organ. This includes surgical entry into tissues, cavities, or organs or repair of traumatic injuries
Medical device	<p>Any instrument, apparatus, appliance, material or other article, whether used alone or in combination (including the software necessary for its proper application), intended by the manufacturer to be used for human beings for the purposes of:</p> <ul style="list-style-type: none"> • diagnosis, prevention, monitoring, treatment or alleviation of disease; • diagnosis, prevention, monitoring, treatment or alleviation or of compensation for an injury or handicap; • investigation, replacement or modification of the anatomy or of a physiological process; and • control of conception. <p>and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.</p>
Needle stick injury	Percutaneous injury with any sharps designed for use in health care that may potentially transmit infectious agents, and in particular blood borne viruses. Sharps may or may not have been used on a patient
Non-critical site	Body site with intact skin. Instruments should be cleaned and disinfected if necessary
Nosocomial infections	Infections that occur as a result of being in a health care establishment, strictly a hospital, but the term now is used more generally refer to any health care setting where infection can be spread from person to person. See also health care associated infection.
Occupationally acquired infection	Infection which was acquired as a result of an injury exposure that was work related
Office practice	The provision of health care services in sites outside routine hospital in-patient and operating theatre settings; such sites include private consulting rooms, health clinics, including mobile health clinics, ambulatory day care centres and outpatient departments. See also Health Care Establishments
Patient	Includes (but is not limited to) a person who is accessing medical or health services, or who is undergoing any medical or health care procedure

Penetration time	For sterilisation by steam under pressure or by dry heat, is the time required for every part of a load to reach the selected sterilising temperature after that temperature has been reached in the sterilising chamber
Percutaneous	Through the skin, as in injection or piercing
Reprocessing	All steps necessary to make a contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilisation. [References: AS/NZS 4815 and AS/NZS 4187]
Reusable item	An item designated or intended by the manufacturer as suitable for reprocessing and reuse. It is not a device that is designated or intended by the manufacturer for single use only.
Semi critical site	Contact with intact mucosa or nonintact skin. Instruments should be sterilised where possible, or [THERMALLY OR] high-level [CHEMICALLY] disinfected.
Sharps	Any objects capable of inflicting penetrating injury, and includes needles, scalpel blades, wires, trocars, auto lancets, stitch cutters and broken glassware
Single-use equipment	Equipment designated by the manufacturer for single use or single patient use only
Skin disinfectant	An antiseptic that is intended for application to intact, healthy skin to prevent the transmission of transient or resident skin bacteria from person to person or from a surgical operation site to underlying tissue. Skin disinfectants include antimicrobial and antiseptic soaps, hygienic hand washes, hygienic hand rubs, surgical hand rubs and surgical hand washes
Soil	Visible dirt or debris that may protect, harbour or assist the growth of microorganisms. Includes organic matter, organic substances, residual soil, inorganic matter, blood and body substances.
Standard precautions	Are work practices required for the basic level of infection control. Standard precautions are recommended for the treatment and care of all patients, and apply to all body fluids, secretions and excretions (excluding sweat), regardless of whether they contain visible blood (including dried body substances such as dried blood or saliva), nonintact skin and mucous membranes. Standard precautions include good hygiene practices, particularly washing and drying hands before and after patient contact, use of protective barriers which include gloves, gowns, plastic aprons, masks eye shields or goggles, and appropriate handling and disposal of sharps and other contaminated or infectious waste and the use of aseptic technique. See also Additional precautions

Sterile operating field	An area specially designed to be free from microorganisms, as used for performing invasive procedures. See also Asepsis, Aseptic technique
Sterilisation	Complete destruction of all microorganisms, including spores
Sterilisation time	The total time of the sterilisation stage after the sterilising chamber has reached the sterilising temperature (penetration plus holding time)
Therapeutic devices	Medical devices used for the purpose of treatment or medical therapy; specifically, for the purpose of this document, devices that may be left indwelling and may provide an infection hazard
Validation	Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield a product complying with the predetermined specifications (Note: validation broadly encompasses three activities – commissioning verification of a process specification and performance qualification). [Reference: AS/NZS 4187 and AS/NZS 4815]

Appendices

Appendix 1

Summary of monitoring and validation of steriliser function

Please note: changes are likely following the introduction of the new standard to replace AS/NZS 4815:2001

Monitoring for moist heat with printers

Monitoring	Frequency
Class 1 Chemical Indicator	On every pack in every load
Class 4,5 or 6 Chemical Indicator	*Every load In each surgical pack
Biological Indicator	At commissioning After a major service At least annually After changes to challenge pack or load
Calibration by a service Technician	At commissioning After major service
Penetration time test	At commissioning After changes to challenge pack or load As part of annual calibration

*not mandatory, however, considered best practise

Appendix 1

Summary of monitoring and validation of steriliser function

Monitoring for moist heat without printers

Monitoring	Frequency
Class 1 Chemical indicator	On every pack in every load
Class 4,5 or 6 Chemical Indicator	Every load
Biological Indicator	At commissioning After a major service At least annually After changes to challenge pack or load
Calibration by a service Technician	At commissioning After major service
Penetration time test	At commissioning After changes to challenge pack or load As part of annual calibration

Appendix 1

Summary of monitoring and validation of steriliser function

Monitoring for Dry Heat Sterilisation

Please note: changes may occur following the introduction of the new standard to replace AS/NZS 4815:2001

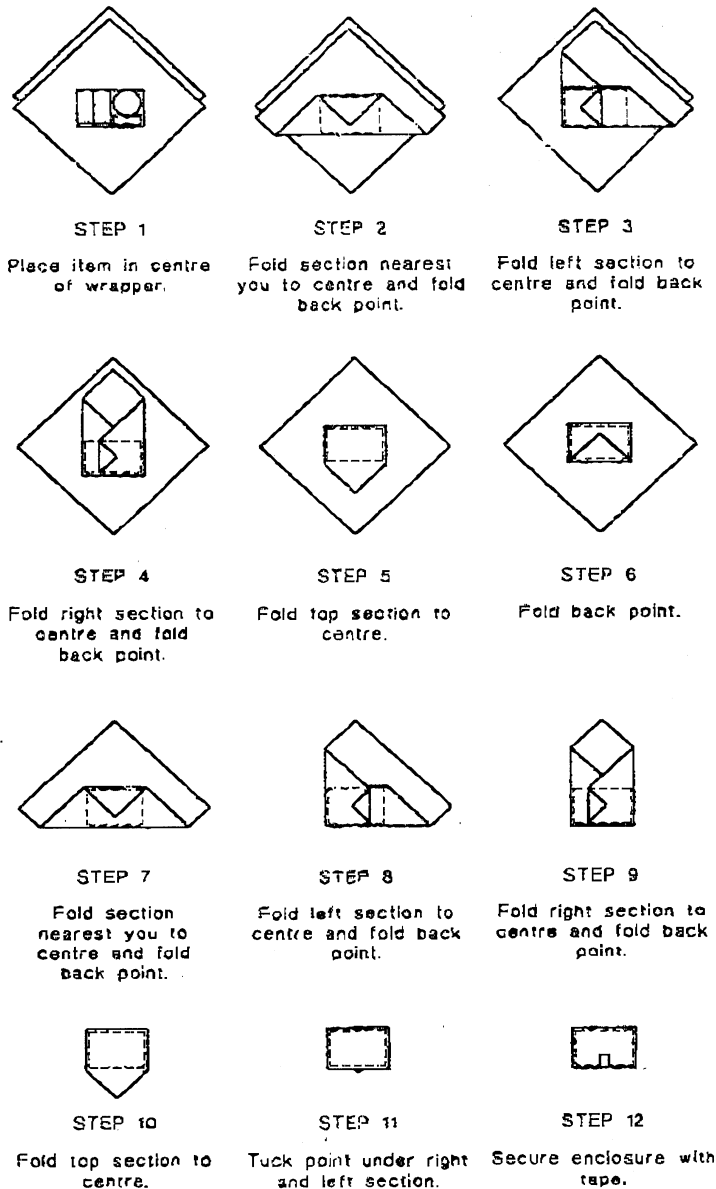
Monitoring	Frequency
Chemical Indicator Class 1 (specific for Dry heat)	On every pack in every load
Class 4 or 6 chemical indicator (specific for Dry heat)	At commissioning After a major service At least annually After changes to challenge pack or load In every load In every pack
Biological indicator	At commissioning After a major service At least annually After changes to challenge pack or load
Calibration by a service Technician	At commissioning After major service
Penetration time test	At commissioning After changes to challenge pack or load As part of annual calibration

Appendix 2

Extract from AS/NZS 4187:2003

Sequential steps for envelope – fold wrapping technique

Extract from AS/NZS 4187: 2003



NOTE: Due acknowledgement is given to ANSI/AAMI ST46—1993

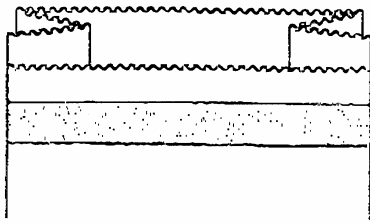
FIGURE 3.1 SEQUENTIAL STEPS FOR ENVELOPE-FOLD WRAPPING TECHNIQUE

Appendix 2

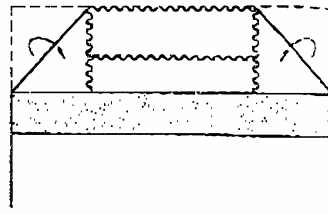
Extract from AS/NZS 4187:2003

Sequential procedure for sealing bags with steriliser indicator tape

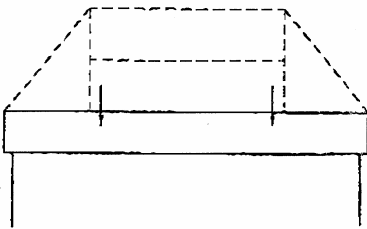
Extract from AS/NZS 4187: 2003



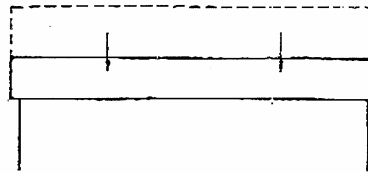
(a) Kraft bleached paper heat seal bag



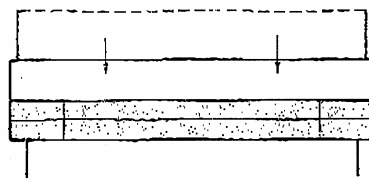
(b) Corners may be mitred



(c) First fold



(d) Second fold



(e) Packaging tape 19 mm-25 mm wide to fully secure fold and extended approx. 25 mm across back of bag.

SEQUENTIAL PROCEDURE FOR SEALING BAGS WITH STERILIZING INDICATING TAPE

Appendix 3

Body and body fluid exposure action plan

Skin	Eye	Mouth	Needle stick / sharps injury
Immediately wash with soap & water	Rinse gently but thoroughly with water while eyes open	Spit out & rinse mouth thoroughly with water	Immediately wash with soap & water
Assess Risk of blood borne virus transmission			
Non or Doubtful Exposure (no breaks in skin, sharp not contaminated with BBF)	Possible Definite Exposure (BBF contamination to broken skin, eye, mouth)	Massive Exposure (Source Hep B, C or HIV positive)	
No further immediate action	<p>IMMEDIATELY CONTACT</p> <p>Medical clinic responsible for Occupational Health Support:</p> <p>Dr</p> <p>.....</p> <p>Telephone:</p> <p>For counselling, blood screening and possible referral to a major health facility with an Infectious Diseases Medical Officer</p>	<p>MASSIVE EXPOSURE</p> <p>Contact major health facility with Infectious Diseases Medical Officer for counselling, blood screen and post exposure prophylaxis</p>	

**Report and document Incident -
Assess cause and develop prevention strategy
Seek Medical Evaluation**



