

Practical Guide to Infection Control

Ninth Edition



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Disclaimer: The routine work practises outlined in these guidelines are designed to reduce the number of infectious agents in the dental practice environment; prevent or reduce the likelihood of transmission of these infectious agents from one person or item / location to another; and make items and areas as free as possible from infectious agents.

Professional judgement is essential in determining the necessary application of these guidelines to the particular circumstances of each individual dental practice.

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Introduction

Strict adherence to recommended infection control protocols forms the cornerstone of modern, safe dental practice. There are documents which are mandatory to achieve this aim. According to the Dental Board of Australia, **possession of these documents at the practice premises in hard copy or their availability via the internet is a mandatory requirement.**

It is also the responsibility of individual practitioners to acquaint themselves with their state or territory's additional mandatory regulations and rules with regard to infection control, e.g. via public health legislation and Environmental Protection (EPA) regulations.

Infection control manual

Every practice must have a specific written protocol which forms the 'how-to' of running the infection control requirements of that practice. It also helps members meet Work Health and Safety and training requirements. This protocol can be written in conjunction with an infection control consultant or a commercially available document can be modified to meet the needs of the particular practice. Alternatively, members can adapt information from the ADA Guidelines and the templates used for Practice Accreditation.

Suggested reference protocol

- Dental Board of Australia: Dental Guidelines on Infection Control
www.dentalboard.gov.au
- Australian Guidelines for the Prevention and Control of Infection in Healthcare, published by the National Health and Medical Research Council (NHMRC) 2010
www.nhmrc.gov.au
- ADA's Guidelines for Infection Control
www.ada.org.au/Publications/guideinfectcont.aspx
- AS/NZS 4815 Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment, or as an alternative,
- AS/NZS 4187 Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities
www.saiglobal.com
- Hand Hygiene Australia
www.hha.org.au
- Australian Commission on Safety and Quality in Health Care
www.safetyandquality.gov.au

To support this document the ADA Infection Control Committee publishes articles for the ADA News Bulletin highlighting matters of current importance. These and other references of note are either listed or available on the ADA website for members

www.ada.org.au

The Practical Guide to Infection Control is a collated series of these articles that have been prepared to assist members and their staff with understanding key issues, establishing protocols and complying with Statutory Authorities.

Hand care

Intact skin (i.e. with no cuts or abrasions) is an important natural barrier against infection. Any breaks in the skin from trauma or various lesions such as weeping dermatitis will be potential entry locations for pathogens. Improper hand care can damage the protective systems of the normal skin (such as its lipid fatty acid layer and commensal bacterial flora), particularly when detergents or solvents are used excessively on the hands.

Cuts and abrasions should be covered by water-resistant occlusive dressings that can be changed as required. Staff who have skin problems such as exudative lesions or weeping dermatitis must seek medical advice and must be removed from direct patient care until the condition resolves.

Unnecessary trauma to the hands should be avoided. Zealous use of scrubbing brushes can easily abrade the skin, as can forceful use of poor quality paper towelling for drying the hands. To minimise chapping of hands, warm water should be used for handwashing, and the hands dried by patting them to blot away surface moisture (leaving the lipid layer intact), rather than by rubbing them, which will abrade the skin surface.

Irritant contact dermatitis in response to wearing disposable gloves is a very common problem for dental staff. This is a non-allergic response, caused primarily by irritation from detergents (such as sodium lauryl sulphate) and disinfectants such as chlorhexidine. Contact with these agents becomes a problem when excessive amounts of handwash are used. Residues left on the skin are held in contact with the outermost layers of the skin because of the occlusive action of the glove material which acts like a dressing.

It is important when handwashing to rinse off all traces of detergent under running water. The hands are then dried gently. **To avoid chapping do not rub and be sure to remove traces of water - particularly between the fingers, otherwise gloves will not slide on.**

Water can be a mild irritant if the skin is exposed to it frequently for prolonged periods of time. Water combined with antiseptics and detergents removes the protective lipid layer on stratum corneum of the skin and as a consequence, liquids can spread onto and penetrate the skin itself. The loss of lipid also increases the rate of trans-epidermal water loss and makes the skin more susceptible to subsequent irritants. This is why the condition becomes self-perpetuating.

Dental staff suffering from irritant dermatitis typically notice an improvement during vacations. However, the problem re-appears when they return to work. The history may reveal that non-occupational factors are contributing, for example, exposure to detergents and solvents domestically can exacerbate the condition. This is the reason why gloves should also be worn when washing dishes by hand after meals.

The appearance of irritant contact dermatitis is typically dry fissured skin, which may become itchy.



The outer layers of the skin can break down and begin to peel into layers. If this develops, the staff member should check their hand care protocol and reduce the use of irritant handwash products whilst improving rinsing and drying of the hands before gloving to remove traces of detergent. Use of a water-based emollient hand cream (not a barrier cream) three or more times daily is also recommended to provide some additional protection. The product chosen should be low in fragrance, emulsifiers and other additives which can cause irritation, and be compatible with alcohol-based hand gels. If these measures do not provide resolution, changing the brand/type of handwash should be considered. Medical assessment is warranted in more severe cases.

While it is harmless, irritant contact dermatitis should not be ignored since its effects on the skin, namely reduced skin integrity, can enhance direct absorption of chemicals from latex gloves, which could accelerate the onset of a true immunological reaction to polymerising agents or to latex itself. This can occur because these components are water soluble and thus when in contact with the skin under occlusive conditions, will dissolve in perspiration and traces of moisture and penetrate into the skin, evoking an immune response.

For handwashing, care should be taken that liquid handwash does not become contaminated with water-borne opportunistic pathogens (such as *Pseudomonas aeruginosa*). This can occur when refillable containers are topped up repeatedly with tap water. Instead, when empty, the containers should be washed thoroughly and left to dry overnight before filling with new solution. Alternatively, use systems with a fully disposable reservoir and nozzle.

Latex allergy

Natural latex allergy (NLA) may have serious consequences for dental staff and patients sensitised to Natural Rubber Latex (NRL). Symptoms may manifest as delayed (type 4) hypersensitivity such as rash, conjunctivitis or rhinitis, which may then progress at some time to an acute allergic (type 1) anaphylactic reaction. Anaphylaxis may result in death.

Latex is the sap from the rubber tree, *Hevea brasiliensis*. As a material, it is comprised of proteins (5%), rubber (cis-1, 4-polyisoprene) and water (60%). Allergenic latex compounds are present in NRL gloves, in addition to various stabilisers and polymerising agents.

The latex protein content of NRL gloves can vary 3,000-fold among manufacturers. Powdered NRL examination gloves have the highest protein content and allergen levels, because corn-starch particles absorb latex allergens (as well as bacteria from the skin), and then cause respiratory exposure to latex proteins when these particles become aerosolised during gloving and degloving. It has been shown that protein/powder particles can remain in the air for up to 12 hours after changing gloves. Powder-free gloves are preferred to prevent the release of fine particles of latex materials into the breathing zone when gloving and ungloving.

NRL gloves rated as 'hypoallergenic' will have reduced levels of polymerising or accelerating agents because of better washing and leaching treatments. The lowest levels of allergens (latex and other substances) will be in powder-free gloves that have undergone additional treatments to remove or alter such allergens such as washing and chlorination.

The use of powdered NRL gloves have the highest allergen levels and therefore the greatest risk of sensitisation and allergic reaction. Powder-free or hypoallergenic NRL gloves and/or non-latex (e.g. nitrile or neoprene) gloves are preferred for routine patient use.

Those who report NLA must be treated (at work, if a health-care worker) in a NRL-free environment. This means that non-latex gloves and dams are used and alternatives must be chosen to rubber prophylaxis cups, rubber bite blocks, and rubber-based impression materials. Additionally, anaesthetic carpules and solutions chosen must be free of latex rubber in their manufacture and be constructed so latex does not contact the solutions in the bungs. Plungers of endodontic irrigant syringes must be latex-free. Protective face masks for staff must not contain latex rubber: tie on masks may be an alternative. Currently, gutta percha is not considered a problem for those with NLA.

All patient medical histories must include questions about NLA and/or sensitivity to latex/rubber products.

Suspected NLA in patients and staff must be treated as a serious medical issue and any testing deemed necessary must be carried out by a clinical medical allergist.

Latex allergy in dental staff

Type 4

Dental staff can manifest a delayed (type 4) hypersensitivity reaction to latex proteins, which may at some future time progress (with repeated exposure to latex) to an acute allergic (type 1) anaphylactic reaction. Symptoms of a type 4 reaction to latex may include conjunctivitis and rhinitis (as well as dermatitis) because of the degranulation of mast cells in these mucosal sites.

There are several routes of exposure which may have led to the latex allergy developing, such as:

- Inhalation of aerosolised latex proteins absorbed onto powder over an extended time. This route of exposure is probably the most significant for dental staff.
- Cutaneous absorption, by direct contact with gloves, particularly if the skin permeability has been increased by loss of normal surface lipids, or if the individual has severe dermatitis.
- Urogenital exposure, by urinary catheters and vaginal examinations.
- Other mucosal exposure, by rectal exams, dental procedures and surgery.
- Parenteral exposure, by intravenous lines.

An emerging latex sensitivity in a dental staff member is a serious health problem with major implications for their future working life. Should an individual develop a severe latex allergy, they will need to use non-latex (e.g. nitrile) gloves for all their work and will have to restrict their exposure to environments where latex proteins may be aerosolised. Skin testing by a clinical allergist can confirm a diagnosis of type 4 hypersensitivity. A test panel of suspected allergens is applied, and the result (the 'patch test') read from 1–3 days later.

Type 1

The most severe reaction to NRL glove materials is true latex allergy, where the eliciting antigen is a small latex protein (>30 kDa in size). A wide number of different latex proteins can be responsible for latex allergy, with seven of these linked to type 1 hypersensitivity, including heveamine, hevein and rubber elongation factor.

The clinical presentation of latex allergy is characteristic of rapid degranulation of mast cells and basophils, and may have an onset ranging from several seconds to 20 minutes. Symptoms and signs include:

- contact itching (urticaria, hives)
- flushing (redness)
- oedema (peri-oral or peri-orbital swelling)

- excessive lacrimation
- abdominal cramping and nausea
- bronchospasm (wheezing)

These may progress rapidly to full blown anaphylaxis (with tachycardia and dysrhythmias progressing to hypotension, collapse and cardiopulmonary arrest). Immediate medical management is essential. Milder reactions may be managed with corticosteroids (such as hydrocortisone) and antihistamines (e.g. diphenhydramine), while anaphylaxis will require life support as cardiac arrest can occur (both oxygen and adrenaline will be administered, with the latter as an intramuscular or intravenous injection).

Staff suspected of having developed latex allergy require expert assessment by a clinical allergist. This may involve both laboratory and skin tests. True allergy can be confirmed by a skin prick test (**not** a patch test) using panels of antigens from glove products. There will be a rapid response which is read in minutes. The positive control is a non-immunological agent which elicits mast cell degranulation, to give a 'wheal and flare' response. The prick test does pose the risk of severe reactions (and indeed even of anaphylaxis), and in the light of this there is increasing interest in various in vitro (laboratory) tests such as the radioallergosorbent test (RAST) which do not pose any risk to the patient. Such tests are safer and more convenient than the skin prick test, but have a lower sensitivity and specificity. A negative RAST result does not formally exclude allergy to NRL.

Latex allergy in patients

Several groups of patients are recognised to be at increased risk of latex allergy:

Those with prolonged mucosal exposure to latex including:

- neural tube defects and spina bifida
- sacral/lumbosacral agenesis
- urogenital abnormalities
- neurologically impaired bladder function
- frequent catheterisation (especially urinary catheters)
- spinal cord injury
- neurosurgery
- cerebral palsy
- multiple major operations, particularly from early childhood

Those with occupational exposure to latex (through wearing latex gloves) including:

- health care workers
- rubber product workers
- hairdressers
- house cleaners
- emergency service personnel
- embalmers

Individuals with atopy (an inherited tendency to develop allergic responses) are those with:

- asthma, atopic eczema, allergic rhinitis (hay fever)
- myelodysplasia

Patients with allergies to foods which share some antigens with latex. These foods include:

- avocado, banana, kiwi fruit, chestnut
- potato, apricot, grape, papaya, passionfruit, pineapple, peach, cherry, tomato

All patient medical histories should include a question regarding latex allergy.

Identification of latex sources

Latex sources in the dental practice should be identified so that exposure can be prevented. These include:

- natural rubber latex gloves
- latex rubber dam
- gutta percha
- rubber base impression material
- relative analgesia masks
- blood pressure cuff tubing
- stethoscope tubing
- rubber stoppers on endodontic files
- rubber prophylaxis cups
- rubber bite blocks
- rubber orthodontic elastics

Other latex sources

Medical products:

- catheters and drains
- dressings and tapes
- tourniquets
- ECG pads
- oximeter probes
- airways used for general anaesthesia
- nasogastric tubes
- bellows of breathing bags
- plungers of disposable syringes

Domestic products made from natural rubber:

- balloons
- condoms and diaphragms
- rubber bands
- rubber components of furniture, upholstery, tools and kitchen utensils

Local anaesthetic solutions

In relation to local anaesthetic solutions used in dentistry, manufacturers have introduced a range of measures to address the potential concern of latex proteins being released from the diaphragm or bung (plunger) of a local anaesthetic cartridge into the solution, thus giving a systemic exposure to the patient when an injection is administered. Current local anaesthetic products have a bromobutyl bung rather than a latex bung, and employ a laminate design for the diaphragm so the solution is in contact with bromobutyl rather than latex. Moreover, the latex used on the distal side of the diaphragm is treated so as to be free of proteins, which normally comprise 5% of the material by volume. In some products, anaesthetic carpules contain no latex either in the bung or in the diaphragm. Prilocaine hydrochloride with felypressin is known to be latex-free.

While the medical literature provides some evidence latex allergens can be released into pharmaceutical solutions contained within vials in contact with natural latex stoppers; there are no reports of studies or cases in which a documented allergy was due to the latex component of cartridges for dental local anaesthetic solutions. Consistent with this, no allergic reactions to latex have been documented in a laboratory proven latex-allergic patient when either prilocaine with felypressin or lignocaine hydrochloride with adrenaline were used.

Latex-free dentistry

For patients or staff with a history of type 1 or type 4 reactions to latex, it is essential to have proper medical assessment and to then use a latex-free environment.

For example:

- non-sterile non-latex gloves, such as nitrile or neoprene for routine procedures
- sterile non-latex gloves, such as synthetic neoprene
- non-latex rubber dam, such as Roeko Flexi-Dam
- latex-free face masks
- non-latex prophylaxis cups
- silicone elastic bands

Recommendations

To prevent the development of allergic reactions to latex, the following measures are recommended:

- Educate all staff regarding the clinical signs and symptoms of occupational skin disease and latex allergy.
- Use powder-free gloves with low extractable protein content routinely rather than powdered gloves.
- Ensure that any areas that may have become contaminated with latex glove powder are cleaned regularly by vacuuming using disposable bags (upholstery, ventilation ducts and plenums, cupboards, telephones, etc).
- Remove any powdered gloves slowly; do not 'snap' them off as this may release allergens into the atmosphere.
- Include a question regarding latex allergy on all new staff employment forms and on all patient medical histories.
- Consider referring patients or staff at high risk of true latex allergy to an allergist for assessment.
- Patients or staff with proven anaphylactic reactions to latex may need to wear a medical alert bracelet and carry self-injectable adrenaline (e.g. EpiPen containing 0.5–1.0 mg of adrenaline).
- Substitute latex-containing products with known latex-free products in the dental operator for the treatment of any known or suspected latex-reactive patients.
- Treat latex-reactive patients as the first patient of the day to reduce the potential for exposure to latex proteins from glove powder in the air. Because gowns can also become contaminated with the same powder, disposable paper gowns should be worn when treating these patients. The dental surgery should be damp dusted immediately prior to the patient appointment to reduce aerosolised materials.

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Risk reduction for sharps

A number of suggestions have been made for the reduction of injury and exposure to blood-borne pathogens. Many operators will have already established safe routines and techniques to eliminate sharps injuries and the associated risks of transmission of infection. Consistency in work practices and the routine adoption of safe working procedures and techniques are the surest methods for reducing the risk of injury and exposure to blood-borne pathogens.

Frequently, dental practice involves the use of sharp instruments in invasive procedures, with exposure of clinicians to blood, saliva and exudates of patients, often under conditions of limited access and poor visibility. The most common procedures in dentistry where sharps injuries to dental clinicians and their clinical support staff may occur are: cleaning up after a procedure; operative procedures involving burs; the administration of local anaesthetic; the disposal of local anaesthetic needles; the transfer of sharps between healthcare workers and some oral surgery procedures.

While there is a theoretical possibility of transmission of infection from patients to staff members with almost all clinical dental procedures where sharps are used, the probability of this occurring can be reduced considerably by using techniques which avoid injury and prevent accidental injury during treatment. Currently, for sharps injuries, the blood-borne pathogens of most concern are the human immunodeficiency virus (HIV), hepatitis B (HBV) and hepatitis C (HCV). The dental practice must have a clear written protocol on the appropriate action to take in the event of sharps injuries and other blood or body fluid incidents involving either patients or staff members.

It is essential to follow up all sharps injuries immediately with appropriate first aid, counselling and serology (for both the source/patient and staff member). Note emergency contact numbers provide information and advice for persons exposed to potential blood-borne pathogens. This information includes advice on prophylactic measures as well as follow up counselling. Dentists should keep emergency numbers for injuries readily available.

Injuries to dental clinicians and their clinical support staff involving exposure to blood-borne pathogens may occur intraorally or extra-orally. The majority of exposures are extra-oral and occur during clean up procedures. Injuries where the skin is punctured from burs left in handpieces whilst sitting in their cradles are a major component of extra-oral exposures, while intraoral exposures are most often caused by local anaesthetic syringe needles and sharp items such as instruments and matrix bands.

Sharps

- Sharps **must** be handled with care at all times.
- Needles **must never** be picked up with the fingers, nor the fingers used to expose and increase access for the passage of a suture in deep tissues.
- Sharp instruments **must not** be passed by hand between staff members.
- Any single-use item or instrument that has penetrated the skin, mucous membrane or other tissue **must** be discarded immediately after use or at the end of the procedure, whichever is more appropriate.
- The person who has used a sharp instrument **must** be responsible for its immediate safe disposal following its use. This **must** be at the point of use.
- Disposable needle-syringe combinations, needles, scalpel blades, single-use razors and other sharp items **must** be discarded in a clearly labelled, puncture-proof container that conforms with *AS 4031* or *AS/NZS 4261* as appropriate.

The following general points should be considered:

- To ensure all risk items are identified, make a list of the types of sharps maintained in the practice (e.g. instruments, scalpel blades, suture needles, glass local anaesthetic cartridges, glass vials, needles, matrix bands, wedges, burs, endodontic files, orthodontic and ligature wires and broken instruments). Distinguish between disposable sharps and reusable sharps, such as instruments. Have a clear plan (ideally in writing) as to how each sharp is dispensed, used and disposed of, and discuss this at a meeting when all staff members are present.
- Review the circumstances of the sharps injuries which have occurred in the practice to identify factors which may have contributed to these incidents and to develop strategies for prevention. For example, are there problems with techniques, equipment, training or supervision?
- Plan procedures involving sharps so all staff members are aware of their role and responsibilities.

Where four handed dentistry is practised it is essential that strict regimens and protocols be established.

- In circumstances where sharps, including needles and scalpels, have to be passed between operator and assistant then all sharps should be passed in a sterile tray or bowl, but never by hand.
- Only clean instruments should be passed from the assistant to the operator. Where it is necessary for contaminated instruments to be reused the operator should select them from their own working area, or they should be passed using a transfer tray.

- Ensure the change-over procedure between patients starts with the removal of sharps from the working area (e.g. starting with the bracket table) with tweezers. This should be done by the operator, who places them into a sharps container. An established cleaning plan will reduce exposure risk if sharps are inadvertently overlooked by the operator.
- Position sharps containers close to the point of use. Dispose of sharps containers when three-quarters full, and do not overfill them.
- Remember gloves have limited resistance to puncture injuries and develop porosities during use, particularly in the thumb and forefinger regions.
- Do not leave sharps in clinical gowns: check gowns carefully before sending to the laundry.

Burs

Dental burs are a major hazard for sharps injuries. Most injuries from burs are puncture wounds which occur on the hand or wrist when reaching past a bur in a handpiece in its holder attached to the dental bracket table.

Bur removal

Burs should be removed from the handpiece as soon as drilling has been completed, or the handpiece (complete with bur) uncoupled and placed on the bracket table. Exposed burs retained in handpieces present an increased risk of injury to chairside assistants as they may be less aware of the presence of the contaminated bur than the operator. Particularly when the handpiece is placed back into a hanger on the side of the bracket table and may have been forgotten.

Bur cover

Using a bur cover is an alternative to removal of burs from handpieces but presents problems during cleaning and sterilisation. Using a bur cover is less preferable than removal of burs.

Movement of staff

Whilst it is necessary for the burs to remain in the handpiece only the operator should need to be in close proximity to the handpiece.

Clinical staff moving in reach of and reaching over handpieces containing burs are at risk of sustaining a bur injury. This is particularly applicable to the low speed handpiece where the bur is more likely to be contaminated with blood and debris.

Flushing turbine handpieces

Some high speed turbine handpieces require a bur (or blank) to be in place in order for the water lines to be flushed after use. Using a well-established routine will reduce sharps injuries. When purchasing new high speed turbine handpieces to those with water lines that can be flushed without needing a bur (or blank). Operators should be responsible for removing all burs from handpieces at the end of a procedure.

Local anaesthesia

- Practise syringe handling procedures as part of ongoing staff education and training.
- Handle syringes with care — only one person should hold the syringe at any one time.
- Retract tissues before injection with a mouth mirror or retractor (not with the fingers).
- During injection, the assistant can stabilise the patient's head position to prevent lateral or other involuntary head movement.
- Keep hands and fingers away from the mouth while injecting.
- Where multiple carpules are required, the syringe should be reloaded whilst it remains in the hands of the dentist. If multiple injections are required then consider whether they could be given at the same time and with an adrenaline-containing solution, prolonging the time of anaesthesia and avoiding the need for re-injection.
- Remove needles with care. Use artery forceps or other holding devices instead of fingers. As an alternative, consider using a local anaesthetic system with a captive needle which does not require disassembly as the needle and carpule holder are disposed of as one unit.
- It is recommended the needle be disposed of immediately after analgesia. Should supplemental anaesthesia be required during the appointment, it is recommended that a new syringe be used (with a new needle and new carpule).

Control of the oral environment

- Poor visibility and lighting are major factors in sharps injury. Use a headlight to improve illumination, in addition to operating lights. Battery operated or fibre-optic head lights are very useful for surgical, endodontic and periodontal procedures and will enhance efficiency as well as safety.
- Use rubber dam where feasible to reduce contamination of the operating field.
- Use suction judiciously to maintain a clear field.

- When not in use, the tip of ultrasonic scalers should be rendered safe (e.g. covered with a sheath or a cotton roll). Following the procedure the scaler tip should be flushed through by the operator who then removes it from the handpiece. If it is not feasible for the operator to carry out this procedure, flushing and dismantling of the scaler should be given first priority when cleaning up, and this should be incorporated into established cleaning routines.

Oral surgery

- If blood is present in the mouth from the surgical procedure, there are several potential causes of injury: scalpels, elevators, wires, sutures, as well as exposed sharp edges of tooth or bone. Injuries such as puncturing of the fingers by wire are more likely to occur in a poorly lit confined space where visibility is further reduced by secretions such as blood and saliva.
- All clinical staff must wear protective glasses with side shields to prevent splash injuries to the eyes.
- The use of fingers as cautionary rests when performing dentoalveolar procedures should be avoided where possible. Do not position fingers below an elevator tip to prevent it slipping into tissues; rather restrict the downward displacement of the tip by positioning the fingers above the tip of the instrument and then use a rotational rather than vertical movement.
- Do not suture 'blind' or attempt to find a suture needle in a vestibule through the sense of touch.
- In areas of limited visibility, use single sutures rather than continuous suturing. The needle can be cut from the suture after tissue penetration has been fully achieved, then the knot tied using instruments and fingers.
- Ensure adequate retraction.
- Maintain a clear field and improve visibility by removing secretions such as saliva and blood with suction.
- Control bleeding during the procedure using ligation, cautery, coagulation or sutures.
- Use appropriate vasoconstrictors as clinically indicated.
- Minimise the use of wiring in awkward and inaccessible sites to reduce the possibility of sharps injury from cut wires.
- Use an experienced and trained assistant for all oral surgical procedures.
- Where appropriate, use a custom-made scalpel blade removal device for detaching blades from handles. Consider using fully disposable scalpels to reduce the risk of injury when removing scalpel blades.

- For major oral surgical procedures some operators prefer to wear orthopaedic gloves or two pairs of gloves.
- Each operator should maintain awareness of their own infectious disease status (HBV, HCV, and HIV).

Instrument reprocessing

- Remove gross deposits of blood, cements and other contaminants from instruments by wiping them at the chairside onto an adhesive-backed sponge. This will reduce the need for intensive cleaning by hand and thus reduce the risk to dental chairside assistants.
- If instruments cannot be cleaned immediately once they have left the chairside, place them in a holding solution (containing detergent) to prevent residues of dental materials or blood drying onto instruments.
- Clean conventional hand instruments using ultrasonic cleaners or thermal disinfectors, rather than by hand scrubbing.
- Where possible during instrument processing use instrument cassettes or trays to minimise the risk of sharps injuries to staff from handling instruments.
- Develop a clear policy on which sizes and types of burs and endodontic files are discarded after use.

Tuberculosis immunity and testing

In recent decades, the use of vaccination as a public health measure has been very successful in eliminating or substantially reducing the rates of vaccine-preventable diseases (VPDs) in the general community, including diphtheria, polio, tetanus, hepatitis B, measles, mumps and rubella. The effectiveness of vaccination can be seen in improvements in child survival and lowered mortality in both Indigenous and non-Indigenous children.

Tuberculosis (TB) is an infection caused classically by *Mycobacterium tuberculosis*, which accounts for almost all cases seen in Australia, and by closely related mycobacteria in the *M.tuberculosis* complex. Typically, the infection affects the lung, resulting in the characteristic symptoms of cough, fever, sweats, weight loss and haemoptysis (bloody sputum), but can involve any part of the body. The disease progresses more quickly in infants, the elderly, in refugees who have lived in crowded and impoverished conditions, and in malnourished or immune compromised patients. In health care settings, TB prevention and control is focussed around infection control measures (including transmission based precautions to prevent droplet and aerosol transmission); employment-based screening for TB immunity; and appropriate anti-mycobacterial therapy for treating latent TB infections in patients to ensure these latent infections do not become reactivated.

Tuberculosis globally and locally

Globally, around nine million persons develop active disease attributable to *M.tuberculosis* infection annually, and approximately two million persons die each year. Data from the World Health Organization (WHO) indicate that of the nine million persons who developed TB in 2013, 56% lived in the South-East Asia and Western Pacific regions. The remainder lived in Africa, India and China. Globally, some 13% of new cases occurred in persons who were HIV-positive.¹ It has been estimated approximately one-third of the world's population, approximately two billion persons, are latently infected with TB. Although those with latent infection do not manifest overt symptoms of active TB and are not infectious, they are at increased risk for developing active disease and becoming infectious at some later point in their lives.

TB is a notifiable disease in all states and territories of Australia. There are around 1,200 cases of TB notified to Australian health authorities each year (five to six cases per 100,000 population), with higher prevalence rates in Indigenous persons living in the Northern Territory, Far North Queensland and northern regions of South Australia. Many TB cases in Australia are in people born overseas (particularly those from Asia, southern and eastern Europe, Pacific island nations, and north and sub-Saharan Africa). The rate of multi-drug resistant (MDR) TB in Australia has been low (less than 2% of notified cases), but has been growing in recent years, particularly in HIV positive patients.

BCG vaccination

Bacillus Calmette-Guérin (BCG) is a live attenuated parenteral vaccine against TB. Because of its mycobacterial nature, BCG also provides some protection against *Mycobacterium leprae*, the bacterium which causes leprosy. BCG is a live vaccine prepared from an attenuated strain of *Mycobacterium bovis*. The vaccine also contains monosodium glutamate (1.5%) and trace amounts of polysorbate 80. The vaccine is given as a single dose, and re-vaccination is not recommended. The vaccine is given intra-dermally into the skin over the deltoid muscle using a 26 or 27 gauge, 10 mm needle with a short bevel. When administered correctly, the intradermal injection will raise a blanched bleb of skin approximately 7 mm in diameter with the appearance of orange peel. A small red papule then forms at the injection site, eventually ulcerating over the following two to three weeks. The intradermal injection technique requires special training, and should be performed only by a trained provider after a proper assessment of the risks and benefits for the individual and prior testing for TB immunity. Adverse events, such as regional lymphadenitis, are less likely to occur when vaccination is performed by trained medical and nursing staff rather than untrained staff.

Unlike most other vaccines used for VPDs, the effectiveness of BCG in preventing disease is imperfect.² BCG vaccination during infancy provides greater than 70% protection against severe disseminated forms of TB in young children. But when given to adults already infected with TB it has little effect on preventing reactivation of the infection. As a preventive measure, the maximum efficacy of BCG vaccine against pulmonary TB in adults is around 80% for skin test-negative adults, based on studies in North America and Europe.³ Following BCG vaccination, duration of protection is difficult to measure because it relies on T lymphocyte responses. Infant vaccination protection is thought to decline slowly over 10 to 20 years. However, memory responses are known to persist for up to 50 years.

Indications for vaccination

BCG vaccination is not routinely recommended for Australian residents. In the list of recommended vaccinations in the current *Australian Immunisation Handbook*³, for persons at increased risk of certain occupationally acquired VPDs, BCG should be considered for healthcare workers who may be at high risk of exposure to drug-resistant cases of TB, in accord with relevant state or territory guidelines. Due to limited evidence of benefit of BCG vaccination in adults and interference of BCG vaccination with interpretation of tuberculin skin tests (TST), routine BCG vaccination of healthcare workers is not recommended. BCG vaccination should be considered for non-immune (e.g. TST-negative) healthcare workers who are at high risk of exposure to drug-resistant TB.

In recognition of the higher prevalence rates of TB in Indigenous populations, BCG is specifically recommended for use in Indigenous neonates who live in regions of Australia where there is a high prevalence of TB. BCG vaccination has been shown to reduce the incidence of pulmonary TB and to provide substantial protection against disseminated forms of the disease in young Indigenous children in Australia. In recent years very high rates of infection among Indigenous persons have been documented in Far North Queensland and northern South Australia. Consequently, BCG vaccine is provided through public health programs for Indigenous neonates in the Northern Territory, Queensland and parts of northern South Australia. State/territory health authorities determine the recommendations for its use in particular areas within those particular jurisdictions.

Following the same logic, BCG vaccine may be considered for infants born to parents who have migrated from countries with a high TB incidence, and is recommended for tuberculin-negative children < 5 years of age who were or who will be staying or living in countries with a high prevalence of TB for an extended period. There is less evidence of the benefit of vaccination in older children and adults. Although the current *Australian Immunisation Handbook*³ suggests consideration be given to vaccination of tuberculin-negative children \geq 5 years but < 16 years of age who may be living or travelling for long periods in high-risk countries (defined as having an incidence > 40 per 100,000 population). For adults travelling to high risk areas, BCG vaccine should preferably be given at least three months prior to entry into areas where TB is endemic.

Contraindications to BCG vaccination

BCG vaccination is contraindicated when the patient is immunocompromised, e.g. known or suspected HIV positive patients; patients receiving corticosteroids or other immunosuppressive therapy (including monoclonal antibodies against tumour necrosis factor- α); and cancer patients receiving immunosuppressive therapy and/or who have poorly controlled malignant disease. However, BCG can be administered at least three months after completion of cancer chemotherapy, provided the underlying malignancy is in remission. BCG vaccine is not given to HIV-infected children or adults because of the risk of disseminated infection. BCG vaccination should be deferred in the presence of generalised septic skin disease, skin conditions such as eczema, dermatitis and psoriasis, or significant febrile illness.

BCG can be given to breastfeeding women, but it is contraindicated in pregnant women since all live attenuated strains pose a hypothetical risk of harm should bacterial replication occur in the foetus. However, there is no evidence that BCG vaccination causes foetal damage. It is not recommended for neonates weighing < 2.5 kg or in the first few months of life.

TB immunity testing using skin tests

The traditional approach used to assess TB status is the tuberculin skin test (TST), also known as the Mantoux test. This test is performed by trained practitioners to screen individuals prior to considering the administration of BCG vaccine. The TST is based on a delayed cutaneous hypersensitivity reaction to purified protein derivative (PPD), and can be used for all individuals except infants aged < 6 months. Only those with a negative TST result (induration < 5 mm in size) can go on to receive BCG. Those who have previously had a large (\geq 5 mm) reaction to a tuberculin skin test cannot receive BCG. The TST is not recommended to demonstrate immunity after BCG vaccination.

There is no consistent relationship between the size of tuberculin reactions after BCG vaccination and the level of protection provided against TB. The test result can be influenced by a number of factors. Results can be suppressed (false negative) due to post-viral anergy, e.g. up to four weeks following viral infections or exposure to live viral vaccines, particularly measles infection and measles-containing vaccines. Multiple numbers of challenges of the individual with TST (annually) can cause a false positive result.

TB immunity testing using blood tests

Newly available blood tests (Interferon-gamma release assays; IGRA) detect TB infection based on T lymphocyte activation under defined laboratory conditions.⁴ Available brands include the QuantiFERON[®]-TB Gold In-Tube test and the T-SPOT[®] TB test. These assays require a sample of peripheral blood, which must be processed within 8-30 hours after collection since the lymphocytes must be viable to respond to the challenge (synthetic peptides representing antigens from *M. tuberculosis*). Errors in collecting or transporting blood specimens or in running and interpreting the assay can decrease the accuracy of IGRA tests.

IGRA tests can be used in place of (but not in addition to) TST. Their major advantages are they do not expose the person being tested to PPD, thereby avoiding the problem of false positive skin test responses. The results from IGRA test, unlike the TST skin test, are not affected by prior BCG vaccination. There are no false-positive results in people who have previously received BCG. A positive IGRA blood test result indicates the person has been infected with TB, but does not indicate whether this is latent or active – such information comes from chest X-rays, sputum samples, and other tests.

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Dental unit waterlines

In recent years, the dental community's attention has been drawn to contamination of dental unit waterlines (DUWL). The presence of bacteria in waterlines has been recognised since 1957. However, at the time it was not considered that the numbers and types of micro-organisms were sufficient to present a significant health problem. This situation has now changed with well documented cases of patients acquiring *Legionella pneumophila* and *Pseudomonas aeruginosa* infections from dental treatment with contaminated waterlines.

All DUWL become contaminated. While the organisms are derived primarily from the water supply (such as the reticulated community water supply), retrograde contamination, that is, from the delivery end of the waterline, can also occur. The contamination of DUWL is a phenomenon related to laminar flow in small bore tubing where the flow in the middle of tubing is rapid, while the peripheral flow is nearly zero. These conditions allow the deposition and growth of a layer of heterotrophic mesophilic bacteria (somewhat akin to dental plaque in terms of its structure) known as a biofilm. Bacteria can break off the biofilm outer layers and are then expressed in the water delivered from the dental unit. Measurement of the level of bacteria in water exiting from a dental unit (colony forming units per millilitre or CFU/ml) gives an estimation of the level of biofilm present in DUWL.

International standards for potable water are typically a maximum of 500 CFU/mL, with coliforms (such as *E.coli*) less than 1 CFU/100 mL. Dialysis standard water has less than 200 CFU/mL. Exit water from DUWL has been measured as high as 18,000,000 CFU/mL, with variations according to the type and age of dental unit and the use of biofilm reduction measures.

DUWL contamination is increased by:

- use of a municipal supply which does not conform to microbial contamination standards
- heating water in the dental unit (such as for the triple syringe)
- water stagnation overnight
- failure to implement measures to reduce biofilm accumulation

Risks

The existence of a possible hazard is not automatically synonymous with unacceptable risk. Nevertheless, there is evidence dental biofilms may contain such organisms as *Klebsiella*, *Nocardia*, *Moraxella*, *Serratia spp.*, *Pseudomonas spp.*, *non-tuberculous mycobacterium* and *Legionella spp.* These organisms can pose problems for immunocompromised and medically complex patients, groups which represent an increasing proportion of dental patients seen in most practice settings.

Elevated rates of seropositivity to legionella have been noted for some dental health care workers (up to 50% in one study), indicating occupational exposure. DNA sequencing technology has been used as evidence in US court cases with patients claiming illness from contaminated DUWL.

Current understanding of the risk is there is low or negligible risk for a healthy patient, and there may be some risk for an immunocompromised patient. Most of the microorganisms found in dental unit water are gram-negative, heterotrophic bacteria that have little potential to cause disease in immunocompetent people.

Current status

A hierarchy of water quality is required for dentistry. Water used for surgical procedures should be sterile; water used for mouth rinsing should be at least of potable standard. Water required for irrigation for tooth preparation and ultrasonic scaling should be of no less than potable standard.

It is recommended that water delivered to patients during non-surgical dental procedures is potable and consistently contains no more than 200 CFU/mL of aerobic mesophilic heterotrophic bacteria at any point in time in the unfiltered output of the dental unit. This is equivalent to the existing levels used in haemodialysis. It is prudent to treat immunocompromised patients using water in which the number of colony forming units < 200 CFU/mL. CFU levels can be measured using commercially available test strips and kits.

For dental units equipped with an independent water supply, the manufacturer's instructions must be closely followed for disinfection procedures.

Air and water lines should be flushed for a minimum of two minutes at the start of each day and for 30 seconds between patients. There should be an extended flush at the beginning of each session, particularly after a weekend or other break.

All dental equipment that supplies water to the oral cavity must be fitted with non-return valves.

Correctly managed, current protocols can deliver water of < 200 CFU/mL. Generally, they are operator-dependent, and many of them require a separate (bottled) water supply not connected to the municipal system. Most current protocols rely on chemical disinfection (e.g. using silver, peroxide, ozone or oxygen releasing systems, or intermittent sodium hypochlorite), or on the supply of sterile water to the dental unit.

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Waterline treatments using silver compounds

With a long history of the use of silver fluoride and silver nitrate as topical agents, the antibacterial effects of silver and its salts have been used in dentistry for many years. Silver in various forms is now used widely to control bacterial growth in dental unit waterlines, ranging from additives to water dosing systems to silver impregnated tubing.

Silver particles, silver ions and silver-based compounds are highly toxic to microorganisms. The antimicrobial effects are due largely to the generation of free radicals, which subsequently attack membrane lipids, leading to a breakdown in membrane function. This membrane attack mechanism explains the broad spectrum effects of silver and the reason why susceptibility to it is not influenced by multi-drug resistance problems. Overall, the effects of silver as an antimicrobial appear to be greater on fungi and gram-negative organisms than on gram-positive organisms. Most waterline biofilm organisms of concern (i.e. *Legionella* and *Pseudomonas* species) are gram-negative. Waterline aerosols which contain *Legionella pneumophila* or *Pseudomonas aeruginosa* can cause pneumonic diseases and wound infections. Water stagnation in dental unit waterlines creates biofilms and promotes the proliferation of these microorganisms.

Silver compounds such as silver nitrate can be used in self-contained water systems for dental units, with commercial products available as tablets and liquid additives. In some tablets, the silver nitrate is combined with a surfactant, and an oxygen releasing agent such as sodium percarbonate (an adduct of hydrogen peroxide).

Silver can also be used in the form of nanoparticles dispersed into water. Reducing particle size is an effective way of increasing the relative contact area. A variety of silver dosing systems for water treatment of self-contained water systems are in current use in dental practice environments. They can also be used to treat the water coming to dental units from reticulated water supplies. A common configuration for the latter is to combine sub-micron filtration and chemical removal using activated carbon with silver dosing into water. The silver can be in ionic or colloidal forms. In the former, silver wires suspended in water pass a small electrical current, which causes silver ions to be released into the water. In the latter, the silver particles are sufficiently small they remain permanently in suspension and do not settle under gravity.

Because silver-based systems work through oxidation mechanisms, they can be combined with other generators of oxygen-free radicals, including hydrogen peroxide and ozone. The combination of silver with hydrogen peroxide hastens the catalytic decomposition of hydrogen peroxide, and creates a silver-oxygen intermediate molecule which is unstable and subsequently oxidises sulphhydryl groups on the surface of bacteria, removing the hydrogen from the S-H bond. This would cause the remaining sulphur bonds to form disulphide S-S linkages, which then impair respiration within the microorganism.

An important comment relates to the safety of silver, given that small amounts of silver will be ingested in water which has been dosed with silver. A side effect of very high consumption of silver is argyria, a greying of the skin caused by the accumulation of silver. This is extremely rare, with only a handful of cases being documented in literature and mostly over 50 years ago from overuse of high concentration silver nitrate nasal drops. There is a long history of the safe use of silver in dental waterline treatments. Current systems which dose dental water with silver give levels of silver in water well below the recommended maximum of 0.1 mg/L.

Water for steam sterilisers

Regardless of the type of steam steriliser used in a dental practice, in order for steam under pressure to be effective for sterilising, it must have a dryness fraction of 97% and above, and not be superheated beyond 2°C of the saturated steam temperature. Steam which is 'wet' (that is, has a dryness fraction less than 97%) is unsuitable for sterilisation and will result in wet instrument packs, while superheated steam will not condense evenly onto the surface of instruments and thus will not transfer the latent heat which is responsible for killing microorganisms.

Older types of steam sterilisers typically employ simple water systems in which water from previous cycles is recycled by condensation of steam at the end of a cycle. Accumulated debris (and lubricants) in this recycled feed water may compromise the performance of the autoclave by causing superheated steam to be produced.

Due to an inevitable deterioration in water quality over successive cycles with reuse, it is essential the water reservoir in such autoclaves is drained completely, cleaned and flushed every week, and then filled with a fresh supply of distilled or de-ionised water (not tap water).

Many modern steam sterilisers use a two tank water system, with a storage tank on the top of the chamber for 'feed' water, and a tank below the chamber for 'dump' water. The latter normally has a waste hose connection. Because these autoclaves do not recycle water between loads, they require a substantial supply of distilled or de-ionised water each working day (typically four or more litres). Therefore, it is necessary to maintain a sufficient quantity of appropriate water for refilling the autoclave as part of the inventory of the sterilising room.

The use of tap water, spring water, ground water, rain water or bore water in autoclaves is contraindicated, since inorganic materials in these waters (such as salts of calcium, magnesium and aluminium) will build up rapidly as a mineral 'scale' in the water and steam lines of the autoclave, and impair the flow of water and steam through the pipes. Distilled or de-ionised water have low levels of these inorganic impurities.

Supplies of de-ionised water can be obtained commercially, as this water is also used for steam irons and lead-acid batteries. Water can also be de-ionised 'on site' using reverse osmosis units. The level of inorganic ions in the exit water from these units can be tested by measuring the electrical conductivity of water. Water with greater levels of inorganic ions is more conductive. If reverse osmosis units are employed the membrane cartridges will need to be replaced on a regular basis to ensure proper operation of the unit.

Management of burs and drills

There are two management approaches for burs:

1. Throw out after one use

Most implant burs are designed and labelled as single-use and cannot be reused. This is the same for any other burs labelled as single-use, including single-use diamond burs. These will be discarded at the end of the visit. Some practices use low cost stainless steel low speed burs for caries removal as single-use items, which eliminates the need to clean and inspect them and also ensures these low speed burs are always sharp when used for caries removal and cavity preparation.

2. Reprocess

Most surgical burs for dento-alveolar surgery are designed for reprocessing and made of materials such as tungsten carbide that do not degrade under sterilising cycling. Tungsten carbide burs and silicon nitride burs are designed for reprocessing, and these constitute a majority of high speed burs. Some implant systems have stainless steel burs and advocate single-use for the smaller 'pilot' drills but tungsten carbide reusable burs for larger preparations. Hence, it is critical to carefully check the manufacturer's instructions.

Many diamond burs are designed for reprocessing. The resin carrier for the diamond does degrade with large numbers of steriliser cycles. Some brands of bur use metal alloys as a matrix/carrier for the diamond particles, providing a very long lasting bur with less loss of diamond particles over time.

Stainless steel burs become blunt after multiple uses and corrode after multiple steriliser cycles, hence when either of those events occur, the bur will need to be disposed of into the sharps container. As per **AS/NZS 4815** and **AS/NZS 4187**, burs must be free of corrosion and still suitable for use in order to be reprocessed. Clinicians need to inspect bur sets for the tell-tale signs of wear and corrosion as they are reprocessed. Corrosion may be seen after the third or fourth cycle of sterilising, especially when a corrosion inhibitor has not been used during reprocessing.

Storage of sterile instrument packs

Clean instrument storage should occur in a clearly defined area, that are protected from vapours; splashing or aerosols produced during equipment washing; ultrasonic cleaning and reprocessing; or from clinical procedures or handwashing. Practically, this means the storage of sterilised items should be outside the sterilising room environment.

Drawers or sealed containers are preferred for storage of sterile wrapped items because they allow the contents to be easily seen. They should be located at a height so the contents can be both easily seen and turned over. The most recently processed items should be placed towards the back of the drawer. It is important the area used to store sterile items be located as far as physically possible from any sources of splash or contamination. This means it cannot be near the sink in the sterilising room. If the area used for storage is too small, too high, crowded or awkward, then problems will occur in correctly accessing the items. The chance of penetration of a sterile pouch by an item will be increased in such situations.

For routine dental instruments, protection from aerosol and environmental contamination can be achieved by storage in bags, covering instruments with an impermeable material, storage in closed drawers, or storage in dedicated covered containers. To facilitate environmental cleaning and prevent contamination, all packaged sterile items should be stored at least 250 mm above floor level. Similarly, sterile items should be stored at least 440 mm from ceiling fixtures to allow unrestricted airflow and to prevent heating and degradation of the packaging material by lighting or direct sunlight.

For sterile packaged items, it is essential the packs be dried by the autoclaving process and maintained in an environment which is clean, dry, and free of sharp objects that may damage the packaging.

Thus, the steam steriliser which is used must dry package sterile items as part of the cycle before unloading, and not produce damp packages at the end of the cycle. This means packaged items should only be processed in a steam steriliser that has a built-in drying cycle. Bench top sterilisers that do not have a built-in drying cycle are NOT appropriate for the sterilisation of wrapped items, but can be used for non-critical unwrapped items. Pre-vacuum steam sterilisers are best for the sterilisation of packaged loads.

During storage, events which can lead to a breach in the packaging and therefore contamination of the contents of a pack include the following:

- **Over-handling of the pack**
Through excessive transferring from one place to another, or during rotation of instrument packs, it is good practice to rotate packaged instruments so those with the latest expiry dates are placed at the rear of the storage drawer or cabinet.

- **Moisture contamination of the pack**

If a dry instrument pack is placed on a wet bench top, or is wet by splashing of water, other liquids or by aerosols, the pack must be deemed to be contaminated and unsterile.

The contents cannot be used for a procedure and must be cleaned and re-sterilised.

- **Penetration**

If during handling any instruments break through the surface of the pack or pouch, this breaches the protection of the pack, and the contents must be regarded as unsterile.

For the above reasons, it is important wrapped instruments before use are stored in a clean dry area, and subjected to minimal handling.

Unwrapped instruments (e.g. instruments in trays) must be stored in a clean, dry, dust-free environment, and must be separated from any possible chairside contamination. This can be achieved using large plastic bins with close fitting lids to eliminate environmental and aerosol-based contamination.

When an instrument pouch intended for use in a surgical procedure is about to be used check the outer wrapping of the package to ensure there are no holes or tears. After the package is opened, and if a Class 4, 5 or 6 indicator has been used internally, it should be checked. If the pouch has a clear plastic side, this check can be done without opening the instrument pack. If there is any doubt whether sterility was obtained during processing, the items should be considered contaminated and not used during a procedure.

Batch Control Identification of dental instruments

Batch control identification (BCI) is used to link packs of instruments or individual items back to a particular autoclave cycle. BCI is not the same as tracing, which refers to being able to identify which individual instruments have been used on a particular series of patients, and gives the location of instruments at any one time.

The underlying logic for BCI is based on the Spaulding classification system, which describes the risk that instruments may transmit infections to patients during clinical procedures according to the site where those instruments are to be used. Contact sites for instruments are classified as critical, semi-critical or non-critical.

Instruments that contact sterile tissue (critical sites) are the highest risk, while instruments used on intact non-sterile mucosa (semi-critical sites) have lower risk, and instruments that contact only intact skin (non-critical sites) pose the lowest risk. Thus, an instrument which is used in clinical practice to intentionally enter or penetrate a sterile tissue, cavity or the bloodstream is classified as critical, and clearly instruments used for surgery in the dental office would fall into this classification.

All instruments and equipment used in critical sites must be:

- sterile at the point of use;
- packaged;
- processed in an autoclave with a dedicated drying cycle using validated cycle parameters; and
- able to be tracked back to a specific autoclave cycle using BCI.

Thus, reusable instruments used for the following procedures require BCI:

- oral surgery, including routine extractions, soft tissue procedures and surgical removal of teeth;
- oral and maxillofacial surgery;
- implant surgery;
- periodontal surgery, including the use of electrosurgery; and
- endodontic surgery.

These situations represent critical procedures in which deliberate surgical entry to sterile tissues occurs. Any instrument that is used to enter tissue that would be sterile under normal circumstances must be sterile at the point of use.

The three key elements of BCI are:

- batch numbering system;
- comprehensive log of autoclave cycles which includes batch numbering data; and
- simple means for recording batch information on patient records.

Because BCI refers to instrument packs or sets, rather than individual instruments, there is a clear logic in re-assessing the inventory of instruments used for surgical procedures. Generally, it will be more efficient to combine several instruments into a set, rather than to keep isolated instruments in separate pouches.

Moreover, in a smaller dental practice where few critical procedures are undertaken, there may be improved efficiency by autoclaving the surgical instrument sets from the day together in the one load (which must employ a drying cycle).


Batch numbers can be a simple sequence of numbers, such as that produced from a labelling gun, or can be combinations of a number sequence with codes for the date and the autoclave number (if the practice has several autoclaves). For example, 05-02-2015-A-07 would indicate the pack was processed on 5 February 2015 in autoclave A, and was the seventh batch on this particular day.

Batch information can be recorded on a pack using non-soluble permanent marker ink or adhesive labels. Commercial labelling guns such as those used in supermarkets can be used, provided the adhesive and the ink tolerate autoclaving. Alternatively, solvent-based felt-tipped marking pens, and rubber stamps with ink can be used for labelling packs prior to sterilisation with information regarding the contents of the pack and the batch data required for BCI.

It is not necessary to place an expiry date on packs, since the modern concept of expiry dates relates to events rather than a specific time. Pencils, water-based markers and ball type pens should not be used for labelling packs as these may compromise pack integrity. Similarly, packs should not be labelled after sterilisation as this may also compromise the integrity of the pack.

At the time of the clinical procedure, batch number information must be recorded into the treatment record section of the patient's chart, along with the usual details regarding the clinical procedure itself. It is the clinician's responsibility to record the batch numbers for critical items in the patient's record when writing/typing in the notes for the procedure.

An alternative to handwritten recording of batch information into the patient's hard copy query chart or record is the use of a segmented (piggyback) adhesive label system. At the time of setting up for the procedure, a part of the label is peeled off the pack and placed directly under the day's entry on the patient's chart. A variety of commercial label systems and labelling guns are available. Some labelling systems include a Class 1 chemical indicator on the label, which changes colour in response to exposure to heat. This provides a useful visual guide that the item has been processed, and is in addition to the Class 1 indicator already included on the pack.



The final component of BCI is a comprehensive log of steam steriliser cycles, which includes information on the batch numbers in various loads. An entry into this log is made for all autoclave cycles, even those which do not include any packs of critical instruments.

This log provides the necessary written documentation of sterilisation and comprises a book with ruled columns with the following headings:

- Steam steriliser identification code (if there are several units in the practice)
- Date
- Time
- Cycle parameters (wrapped, unwrapped, etc.)
- Nature of the load (numbers of packs, instrument cassettes, etc.)
- Batch numbers of packs included in that load (if any)
- Identification of the loading operator
- Result of the autoclave readouts or printout for that cycle
- Result of the chemical indicators (Class 1, 4, 5 or 6) used in the cycle
- Identification of the unloading operator who has checked the autoclave readouts and chemical indicator result, and who authorises release of the load for use.

Data for physical steam steriliser parameters can easily be obtained if the autoclave has a printout. All new autoclaves have printing or data transfer capabilities. When selecting a printer, ink-based printouts are preferred to thermal printouts as there is less likelihood of degeneration and fading over time. Since it is necessary to keep printouts for a specific period (typically seven years), it is important the readouts are still legible after this time.

Chemical indicators which change colour when correct sterilising conditions have been achieved must be used on the outside of packs and pouches of critical items. Examples of these process indicators (Class 1 chemical indicators) include inks which change colour when incorporated into the paper of an autoclave bag or pouch, and tape with diagonal stripes is used to either seal packs or as a specific indicator.

Validation of bench top sterilisers

Introduction

The underlying principles come from the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* (NHMRC 2010), *AS/NZS 4815*, *AS/NZS 4187*, and the *ADA's Guidelines for Infection Control*.

Installation qualification

Installation qualification (IQ) is the process of ensuring a new or re-installed steriliser is correctly installed as per specifications. IQ is normally part of the initial installation but may also be required due to relocation of the equipment within a new context or location. The IQ process should also take into account step-by-step instructions being provided for normal use; alerting the users to fault conditions that may be applicable; the normal maintenance and calibration processes; and contact details for any technical support required for the operation of the steriliser.

Who does this:

For initial purchase, IQ will be undertaken by the supplier's installation technician. For re-installation, the original installer or another suitably qualified technician familiar with the steriliser and who has been trained in its specifications should conduct the IQ and supply documented evidence to the practice.

Operational qualification

Operational qualification (OQ) is a process which ensures the installed steriliser is operating within its intended use parameters and limits. This process involves determining the physical parameters within which the steriliser will perform its intended purpose of sterilisation as per its specifications when used in accordance with the manufacturer's operating instructions and normal operating procedures of the practice. OQ is conducted with an unloaded steriliser to ensure the physical parameters of a normal cycle are well described and understood, including measuring and documenting the physical parameter dynamics within the sterilising chamber. To ensure this is correctly assessed, it is expected that calibrated thermocouples or an equivalent alternate method of assessment of the physical parameters is used to measure chamber dynamics.

Who does this:

OQ is normally performed by a trained technician, and will frequently be a part of the initial installation.

Performance qualification

Performance qualification (PQ) according to *ISO 14937*, is "the process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting specifications".

PQ can only be accurately performed after a thoroughly documented process of OQ.

The intention of PQ is to ensure the performance is robustly demonstrated for real world load conditions so there is confidence the intended sterilisation will occur on each and every occasion the parameters are used. PQ is intended to protect patients from ultimate failure in the sterilisation processes. The full assortment and range of items which are intended or likely to be sterilised must be part of the PQ process – using the appropriate packaging to ensure realistic challenges to air removal and steam penetration. PQ includes both active and passive indicators, the results of which contribute robust evidence to support the normal operation of the steriliser. Placement of indicators should reflect the worst case chamber dynamics determined from the process of measurements taken during the OQ.

Who does this:

OQ is normally performed by a trained technician and will frequently be part of the initial installation processes. HOWEVER, if a dental practice cannot have a technician present, then PQ can proceed provided sufficient passive (chemical) and active (biological) indicators are used to ensure all parts of any load to be sterilised will be sterilised by the normal operational cycle of the steriliser. Whenever in doubt, additional cycle safety is preferred. This is achieved by using additional holding time in order to gain those safety margins.

Using biological indicators

Whenever instruments are packaged, it is essential to determine which steriliser cycle parameters are required for successful air removal and steam penetration. Validation of these conditions is necessary when there is a change in the type of packaging material. *AS/NZS 4815* and *AS/NZS 4187* specify validation must be repeated annually, even when there has been no change in the type or method of instrument packaging. Validation of cycle parameters involves using multiple biological indicators.

A typical wrapped load is prepared. If long thin plastic-paper pouches are used, three indicators are placed and spread evenly through the pack (one placed at either end and one in the middle of the pouch). If larger packs are used, then five indicators, with one in each corner and one placed centrally, would be more appropriate. The test pack with multiple indicators must be prepared in triplicate so that one can be processed on each of three consecutive cycles. A tenth indicator is not sterilised, but rather is used as a positive control.

The test package is placed in the known cold spot of the steriliser chamber and a wrapped load cycle completed. Immediately repeat this process with new challenge packages for two sequential cycles, after which all the spore tests are incubated as well as a non-autoclaved positive control.

The results should be examined by two staff members and a written entry made into the steriliser cycle book, which is then signed off. If all the sterilised indicators show inactivation of the spores (no germination and thus no colour change), then the penetration time chosen with that particular type of packaging and load configuration is adequate. If one or more indicators from the challenge packs show microbial growth, the holding time at 134°C should be extended by two minutes and repeat the entire process. A number of factors can contribute towards a failed result and these should be considered. Common issues to consider include, the wrong type of packaging material, excessive layers of packaging and a cycle time which is too short to allow sufficient removal of air and penetration of steam.

Use of conventional versus rapid readout biological indicators

Once the validation process has been undertaken, the spore vial is activated by closing the cap and crushing the vial to release the spores into the growth medium. It is then tapped three to four times on the bench top to disperse the spores evenly into the solution and then placed into the incubator.

Conventional spore tests rely on the visual colour change in a pH indicator, such as bromocresol purple, which changes from purple (pH 6.8 and above), to yellow (pH 5.2), thus indicating production of acidic wastes by viable bacteria. Using these indicators requires an incubation time of 48 hours at 55°C. In contrast, rapid readout spore tests utilise surface enzymes of spores which cause a change in a fluorescent substrate, which is then detected by an ultraviolet spectrophotometer, giving a three to four hour turnaround. Eventually, these indicators will also undergo a pH reaction as waste products accumulate from growth of microorganisms. This will be a visual colour change from purple to yellow at 48 hours.

Routine steriliser cycle record keeping

The log of autoclave cycle data is an essential part of quality control processes, as it provides the necessary written documentation of sterilisation, and includes parameter information on the batches processed. An entry into this log should be made for all steriliser cycles, regardless of whether or not they include any packs of critical (e.g. surgical) instruments. The log comprises a book with ruled columns with the following headings:

- Date
- Time at the commencement of the steriliser cycle
- Cycle number in that day
- Cycle temperature and time parameters (which will differ according to whether the load contains wrapped items or unwrapped items)

- Nature of the load (numbers of packs, instrument cassettes, etc.)
- Batch numbers of packs included in that load (if any)
- Identification (signature or initials) of the loading operator
- Result of the autoclave physical readouts or printout for that cycle
- Result of the particular chemical indicators (Class 1, 4, 5 or 6) used in the cycle. This checking should include all external and internal chemical indicators; and
- Identification (signature or initials) of the unloading operator – the person who has checked the autoclave readouts and chemical indicator result, and who authorises release of the load for use

A separate record book should be kept for each steriliser, if several sterilisers are used in the practice. It is also prudent to compile a list of names, initials and abbreviations of operators of the steriliser, for reference purposes.

Data for physical parameters can be easily obtained if the steriliser has a printout or electronic data capture. When selecting a printer, ink-based printouts are preferred to thermal printouts as there is less likelihood of degeneration and fading over time. Since it is necessary to keep printouts for an extended period, it is important the readouts remain legible over prolonged periods of time. Chemical indicators cannot be stored as they are not designed to be of archival quality, and the colour changes may not be stable over extended times.

Monitoring steam sterilisers

There are several types of steam-under-pressure sterilisers (autoclaves), for example, downward displacement, assisted air removal, and pre-vacuum. All steam sterilisers must meet the requirements of *AS 2192*, *AS 1410* or *AS 2182*, and be operated according to *AS/NZS 4187* and *AS/NZS 4815*. An autoclave used to sterilise wrapped items must have a dedicated drying cycle.

Regardless of the type of autoclave used, in order for steam under pressure to be effective for sterilisation, it must have a dryness fraction of 97% and above, and not be superheated beyond 2°C of the saturated steam temperature. Steam which is 'wet' (that is, has a dryness fraction less than 97%) is unsuitable for sterilisation, and will result in wet instrument packs, while superheated steam will not condense evenly onto the surface of instruments and thus will not transfer the latent heat responsible for killing microorganisms.

This emphasises the need for the thermocouples in autoclaves to be calibrated to the correct point.

Correct loading of the autoclave chamber is essential to ensure sterilisation because load content and positioning influences removal of air and steam penetration. Efficient air removal from the chamber and load will permit total steam penetration and allow proper drainage of condensate. Correct loading will also reduce damage to packs and their contents and maximise the efficient use of the steriliser. To ensure air removal, hollow items should be tilted on their edge in a draining position. Hollow items packed in pouches should be positioned with the opening against the paper and not the plastic. Similarly, laminate (paper-plastic) pouches should be loaded on the edge of the paper. Racks are useful for gaining adequate separation of packs in this 'toaster rack' configuration. If not in racks, these laminate pouches should be positioned flat in single layers with the paper surface downwards, and never stacked. Items should not touch the chamber walls.

Older autoclaves do not have a drying cycle incorporated into their design. Units without a drying cycle are only appropriate for sterilisation of unwrapped items. All new autoclaves are expected to have a drying cycle and a printer for recording cycle parameters. It is no longer acceptable to crack open the door of the steriliser to assist in drying of the load contents.

Pre-vacuum autoclaves give the most reliable and efficient drying of instrument packs. Also, they provide a more effective method of air removal thus hastening steam penetration.

Newer models of benchtop sterilisers also have printout facilities for monitoring temperature and pressure (as applicable) and holding time. Existing, older-style benchtop sterilisers should be fitted with a mechanism to allow the observation and immediate transfer of information (e.g. time at temperature, temperature, pressure)

to an electronic data storage facility, rather than having to assign a staff member the onerous task of continuous cycle recording (at 10 second intervals), or following the expensive option of using a biological indicator with each cycle.

Modern autoclaves typically use single phase water systems, which do not recycle water between loads. Recycled water from previous cycles causes deterioration in the water quality for each successive cycle. Accumulated debris (and lubricants) in recycled sterilising feed water may compromise sterility (e.g. by causing the production of superheated steam). Thus, in an older autoclave which recycles water, the water reservoir should be emptied, cleaned and flushed each week, then filled with a fresh supply of distilled or deionised water.

At the end of the autoclave cycle, a visual inspection is necessary to ensure the necessary parameters were reached (by checking the printout) and the chemical indicators in the load have undergone the required colour change.

Directly after the sterilising process, items are very vulnerable to contamination by moisture or improper handling. Cooling items must not be placed on solid surfaces, as condensation from water vapour (which is still within the pack) may result. Similarly, if a plastic dust cover is used, the item must be allowed to cool before being placed in the dust cover.

Verification of performance

Sterility is defined as the state of being free from viable microorganisms. For an item which has been terminally sterilised, the theoretical possibility of there being a viable microorganism present on or in the device must be less than one in a million. This probability is termed the Sterility Assurance Level (SAL).

Evidence that a device or instrument is sterile comes from the validation process, and from information gathered about the cycle parameters from printouts and chemical indicators. This comprehensive approach provides assurance that all items which are used in surgical procedures have been treated to the SAL.

Validation is performed to assess the reliability of the sterilisation process. The term validation refers to the total process, which comprises commissioning (installation qualification and operational qualification) and performance qualification (using physical and microbiological indicators). During the commissioning process, the installation technician will document and record a range of physical parameters, check the calibration of sensors and readouts, using measuring equipment certified by the National Association of Testing Authorities (NATA). The operational qualification will involve specific performance tests, for example, using process challenge devices and biological indicators, as well as thermocouples (to assess heat distribution if this is not known).

Performance qualification aims to establish that the minimum SAL of one in one million can be achieved. This requires placing biological or enzymatic indicators inside the largest or most difficult pack to be sterilised, when located in the coolest part(s) of the steriliser chamber (as identified from a heat distribution study, usually the drain at the lower rear aspect of the chamber).

Biological or enzymatic indicators can be placed adjacent to temperature sensors within the chamber and packages. The location of chemical and biological indicators in a package should match its shape, for example, three indicators in a rectangular-shaped pouch, and five indicators in a large square pouch (one in each corner and one in the centre). Reproducibility within acceptable limits is checked by using a minimum of three consecutive identical cycles as part of the validation process.

Thus, the test pack with multiple biological indicators must be prepared in triplicate so that one can be processed on each of three consecutive cycles. Where the parameters are appropriate for the removal of air and the penetration of steam, all the autoclaved indicators should show no colour change. In other words, they should indicate complete killing of the spores. If there is a colour change, which signifies a failed test result, the holding time for the autoclave should be increased in increments of one or two minutes, and the entire validation procedure repeated, in order to establish the minimum time required.

The results of the validation process must be recorded.

The information should include:

- date of the test
- brand and type of packaging system tested
- type of biological indicator used and the batch number. It is important to ensure prior to the validation process the biological indicators to be used have not expired
- location and number of the autoclave (if there are multiple autoclaves in the practice)
- name of the operator running the validation tests
- exact parameters which have been validated

The analysis of the data obtained during validation will demonstrate that a given sterilisation cycle in a particular autoclave will, or will not, render a specified load sterile. Therefore, validation is related to the type of load and to its arrangement in the autoclave chamber. Because of this, validation should be repeated every time significant changes are made in the type of load or type of packaging. If there are no changes in these, performance requalification is still required at least annually.

Routine monitoring of cycles

Saturated steam is an efficient means for killing microorganisms due to its ability to quickly transfer heat energy onto the items being sterilised. As saturated steam condenses, this heat is transmitted onto the surface and the microorganisms are inactivated by direct thermal effects. For sterilisation to occur, the steam must be saturated. The correct level of saturation is achieved by conditions of pressure and temperature. If the appropriate temperature and pressure are not present, the steam will be dry in which case it will be superheated or it will be wet or supersaturated. Both of these impair the sterilising process. Superheated steam is too dry and gives insufficient pressure, and thus poor penetration. Steam which is too wet, or which is a mixture of air and steam, gives too high a pressure and will not condense onto a surface.

Statistically, a sterilising cycle is designed so that the opportunity for a microorganism to survive is less than one in one million. Currently, it is recognised the range of parameters which affect the efficiency of steam sterilisation go beyond the traditional parameters of temperature, time, steam saturation, steam purity and air availability to include a number of items not associated with the process, but rather the product. These include parameters such as bio-resistance, which is the difference between various species of microorganisms to steam sterilisation; bio-quantity, the amount of organisms present; bio-shielding, which indicates where an object has a very low permeability to air or steam; bio-state, which refers to the biological state of the organism, for example, a spore rather than a vegetative organism; and thermos-density, which refers to the heat capacity of the object. A large and heavy instrument may require a considerable degree of heating to raise it to the sterilising temperature, while a small object can be heated very quickly.

Sterilisation cycle performance must be routinely monitored. For existing autoclaves without a printer, a biological indicator or a Class 4, 5 or 6 chemical indicator **MUST** be used with every load (**AS/NZS 4815**). If there is a printer, a chemical indicator of the same class may be included inside each packaged item. In all autoclaves, a Class 1 indicator (autoclave indicating tape or colour change dye) must be used on the exterior of every packaged item. The test frequency and other details relating to the use of indicators are specified in **AS/NZS 4815**.

It should be noted additional tests are required for pre-vacuum autoclaves (e.g. a daily process challenge device for assessing air removal such as the Bowie-Dick test or Helix test, and a weekly air leak test), as detailed in **AS 1410**. The types of chemical indicators used will depend on the configuration of the autoclave. In conventional downwards displacement or assisted air removal autoclaves, these air leak and air removal tests are not required.

Key aspects of sterilisation quality control include checking autoclave readouts for temperature, time and other parameters at the end of every cycle, and using chemical indicators on a routine basis. Data for physical autoclave parameters can easily be obtained if the autoclave has a printout. Modern autoclaves are expected to come with printing or data transfer capabilities. When selecting a printer, ink-based printouts are preferred to thermal printouts as there is less likelihood of degeneration and fading over time. Since it is necessary to keep printouts for a specified period (typically seven years), it is important that the readouts are still legible after this time. In contrast, the cycle log books should be kept indefinitely.

Performance data for every autoclave cycle must be recorded in a log book. The batch code on a packaged item must be able to be tracked back to a specific autoclave cycle entry in the log book. The log book entry for each cycle should document the following: date; steriliser number or code (if there is more than one steriliser within the practice); cycle or load number on that day; cycle parameters (time, temperature and pressure); specific contents of the load, for example, packs, instrument cassettes; batch number(s) in the load; readout result of the printout; readout result of the chemical indicator(s); name or identification of the person who loaded and unloaded the cycle and who authorises release of the load. There needs to be a record of the release of the items to allow traceability, recall of compromised items, and quality management, as well as for medico-legal purposes.

Log books and the related printouts should be maintained for at least seven years (or as defined by state regulations or local policy). Printouts should be initialled by the staff member reviewing them. Retention of chemical indicators is not a substitute for a permanent record of a sterilising process, because exposed chemical indicators may change with time and therefore are not a reliable record.

Chemical indicators

Chemical indicators are designed to give information regarding the performance of the steriliser during the holding phase of the sterilising cycle. This holding phase is the time period during which the micro-organisms are inactivated. Chemical indicators are convenient to use, are relatively inexpensive and provide immediate results. Because chemical indicators are type-specific, it is important to select these according to the autoclave parameters used in the dental practice.

Special attention must be given to proper placement of chemical indicators within larger packs. They should be placed in areas which are most likely to entrap air. When a plastic-paper pouch is used, the indicator should be placed in such a way that it can be easily seen when the pouch is inspected.

Integrating chemical indicators can provide useful information on steam saturation, steam purity and steam availability. It is important to remember with steam saturation that whether water exists as a liquid or as a gas is entirely dependent upon the temperature and the pressure. When the pressure is increased, the boiling point of water is elevated. In an autoclave, it is essential that the steam be very close to the phase change temperature or boiling point. If the temperature is higher than this, the steam is superheated which impairs its ability for killing. There are several reasons for this. Firstly, when saturated steam comes into contact with a cooler object, such as an instrument, the steam immediately changes to liquid water.

This phase change is associated with the release of a large amount of energy in the form of heat. This transferred heat rapidly increases the temperature of the object involved. Secondly, when the steam changes back to water, there is a dramatic reduction in size.

This contraction pulls in yet more steam to replace what has already changed to water. This process continues until the entire load in the steriliser has been raised to the same temperature as the steam.

The third reason relates to the moistening effect. When steam changes to water, organisms are moistened which increases the kill rate. When steam is superheated, the temperatures fluctuate around the chamber and result in an inconsistent killing. Transfer of heat is less, shrinkage of steam is less, and for these three reasons, superheating of steam is a problem.

Class 6 chemical indicators can indicate the presence of superheated steam. The problem of superheated steam can also be detected by placing a range of thermocouples throughout the autoclave chamber, but this is not a practicable method in a dental practice.

An important parameter in effective autoclaving is the purity of steam. Pure steam is pure water in a gaseous phase. Any impurities in steam could be of a liquid form, for example, droplets of water or fog, or they may be of a gaseous nature, for example, entrapped air.

Solid impurities in steam, such as particles of rust or instrument coatings, can also occur. Small amounts of air present in steam as an impurity have little effect provided the air is mixed thoroughly with the steam and the amount of air is very low, for example, less than 1%. If the air is present at a level beyond this, the air does not readily mix with the steam, but remains rather compressed by the steam into pockets of cool air. Cool air pockets, which may be caused by an overcrowded chamber; incorrect wrapping; incorrect positioning; or incorrect use of packaging materials; and are a very common cause of failed autoclaving in downwards displacement autoclaves.

Air pockets occur less often in pre-vacuum autoclaves. A Bowie-Dick test is used to detect the presence of air pockets in a test pack. When water droplets or fog are present as an impurity in the steam, materials inside the steriliser may become wet. The presence of a very small amount of entrained moisture, for example, less than 2%, is beneficial since this reduces the tendency of the steam to otherwise superheat.

The third parameter of steam availability is affected by instrument factors. The most common is a clogged filter in the steam line itself. It is important to remember chemical indicators have specified performance limitations according to the class of indicator. Where instruments are intended to be sterile at point of use, then a high level emulating indicator is required in each instrument pack. While *AS/NZS 4815* permits chemical indicators between Classes 4 and 6 to be used for such a purpose, a Class 6 indicator is preferable because of its ability to provide additional information on steam quality which is not provided by Class 4 and 5 indicators.

The performance of different types of chemical indicators can be summarised as follows:

- **Class 1 indicator**, also called a process indicator, is located on the outside of a package to show whether the item has been exposed to a sterilising cycle. Examples of Class 1 indicators include, inks which change colour incorporated into the paper of an autoclave bag or pouch; and tape with diagonal stripes used to either seal packs or as a specific indicator.
- **Class 2 indicator** is used to measure the effectiveness of air removal. This is also known as a process challenge device. For a pre-vacuum autoclave, an air removal test such as a Helix test or Bowie-Dick test must be run daily to test the ability of the vacuum pump system to remove air adequately.

The procedure for running a Bowie-Dick test can be described as follows:


1. Use the Bowie-Dick test for the very first cycle of the morning, once the autoclave has been warmed to its normal operating temperature. No other items are loaded into the chamber for this test.
2. The Bowie-Dick test pack can either be made or can be purchased already configured.
3. Place the Bowie-Dick test pack horizontally onto a perforated tray above the chamber drain, at least 100mm from the door.
4. At the completion of a vacuum cycle, the pack is removed and the test sheet removed from the centre of the test pack.

This is unfolded and the colour change on the indicator tape on the inside of the pack is compared with that provided by the manufacturer.

An uneven colour change indicates problems in air removal and steam penetration which must be further investigated. The Bowie-Dick test should show a consistent colour change across all areas of the test pack. The results of the test need to be recorded into the autoclave log book and signed off by the operator.

- **Class 3 indicator** is a single parameter indicator with a fairly poor accuracy. A typical Class 3 indicator has an accuracy of 2°C only, and is only used with dry heat sterilisers.
Class 4, 5 and 6 indicators are multi-parameter.
- **Class 4 indicator** provides a graded response with a gradual colour change. It has an accuracy of 2°C in temperature and 25% in terms of time.
- **Class 5 indicator** is sometimes called a Biological Emulator because it is timed to change colour at the kill point for spore tests, which is 1.8 minutes at 134°C. These have a tolerance of 1°C on temperature and 15% on time. A Class 5 chemical indicator offers no safety margin as this indicator is designed to show a pass at a point well before the desired cycle parameters have been achieved. At a temperature of 134°C this is 3.5 minutes. It is at this point that the probability of remaining residual viable organisms is less than one to a million (the sterility assurance level).
- **Class 6 indicator** is sometimes referred to as an Emulating Cycle Verification Indicator, and several common products are used for this purpose. These indicators have a narrow transition period with a 5% tolerance on time and 1°C tolerance on temperature. They typically change colour at 3.5 minutes at 134°C at the sterility assurance point. These indicators will not show a colour change if the temperature is 1°C below. They may also provide an indication on the quality of the steam, for example through bubbling of the laminate on the indicator of the steam if too wet, and producing a brown colour if the steam is too dry or superheated.

It is essential the chemical indicator which is used is certified to international (ISO) standards. Class 6 chemical indicators are certified to ISO11140-1. They are labelled to indicate the specifications, for example, 134°C for 3.5 minutes or 120°C for 15 minutes. Include a chemical indicator in each pack or pouch for instruments intended to be sterile at point of use. While the standard specifies this can be a Class 4, 5 or 6 indicator.



Class 6 indicators are preferred because of their much tighter tolerance to the conditions of steam, temperature and time.

A typical Class 6 indicator will give a colour change at 134°C for 3.5 minutes at the correct level of steam dryness.

The colour change expected for these indicators is both marked on the strip itself and provided on a reference chart from the manufacturer.

Biological indicators

Biological monitoring of sterilisation is based on the use of highly heat resistant spores such as those from *Geobacillus stercorophilus*. These spores provide a greater challenge to the steam sterilising process than will be the case with the organisms present on cleaned instruments. This overkill phenomenon is fundamental to the probabilistic definition of sterilisation which is used by manufacturers and regulators. This is the sterility assurance level (SAL) mentioned earlier.

The intention of chemical tests is to provide information on the process associated variables. In contrast, biological indicators provide some information on product associated variables in steam sterilisation. Because of the probabilistic nature of autoclaving, chemical indicators which can give a parallel, or indeed go beyond biological indicators, are very useful, and these types of indicators are becoming commonly used in dental practice.

Immunisation

It is recommended that dental health-care workers be immunised against: hepatitis B, measles, mumps, rubella, varicella, influenza and maintain immunisation against diphtheria, tuberculosis and tetanus. Additional considerations for immunisation may include poliomyelitis, pneumococcal disease, hepatitis A, meningococcal disease and typhoid. Dental health care workers who practise exposure-prone procedures should know their own potential blood-borne virus status.

Under the Dental Board of Australia (DBA) guidelines, dental practitioners are required to be aware of their infection status for blood-borne viruses. They must seek expert advice appropriate for a dental practitioner infected with a blood-borne virus, for example, from a medical expert or an advisory panel if diagnosed with a blood-borne virus, and cease to perform exposure-prone procedures if viraemic with hepatitis B, hepatitis C or HIV.

Like many healthcare workers, dentists are at risk of exposure to many common vaccine preventable diseases (VPDs) through contact with patients. In addition, they may be exposed to VPDs in the communities in which they live and travel. Therefore, vaccine recommendations must take into account the risk of the individual's exposure for all VPDs. A dentist's personal state of health may require additional vaccines that are not required by other adults, to protect them against infections.

Although most dentists will already be immune to the typical childhood VPDs from routine immunisation or infection, it may be prudent for them to check their immunity by serology and vaccinate accordingly. VPD infections in adults tend to carry a higher mortality and morbidity, it would be unfortunate to become a victim to something as ordinary as measles or mumps due to lack of immunisation.

The Australian Immunisation Guidelines recommend all healthcare workers be immunised against hepatitis B, measles, mumps, rubella, and influenza. In addition, every adult should maintain diphtheria and tetanus immunisation throughout life.

The current edition of *The Australian Immunisation Handbook* is available at www.health.gov.au

The Immunise Australia website provides further information and resources on its website www.immunise.health.gov.au.

Depending on their individual health and situation, dentists should also consider immunisation against poliomyelitis, pneumococcal disease, hepatitis A, meningococcal disease and typhoid.

Regular surveillance for tuberculosis infection may also be appropriate in some circumstances; using immunological tests for responsive lymphocytes (e.g. Quantiferon Gold test) rather than repeat skin testing (Mantoux test), since the latter causes false positive results when frequently repeated.

The dental laboratory

It is important to remember infection control does not stop at the chairside. Items or materials placed in a patient's mouth and subsequently removed and processed elsewhere can be considered biologically contaminated and must be handled in a safe manner. Everyone involved in the provision of dental treatment should be aware there is a small but significant potential for transmission of infection when dealing with dental laboratory work.

It is also essential staff are protected from accidental exposure to contaminated material. It is impossible to guarantee an impression is perfectly clean and free of blood and saliva; many of the items generated in the clinic cannot be rendered biologically safe. If there are residues of blood and saliva on an impression and this impression is poured by someone with a cut on their hands and no barrier protection then a risk exists of developing an infection from a blood-borne virus such as hepatitis C. It is a very small risk but there must be protocols for handling these items at every step, both at the dental surgery and at the laboratory.

In simple terms, clinicians should ensure work is as clean as possible. There should be a protocol for transfer of items between the dental surgery and the laboratory. Dentists and dental laboratory managers need to liaise to ensure all are aware of infection control procedures.

Infection control against blood-borne viruses is based on the premise that in order for a person to be infected, **ALL** of the following three conditions must be present:

- A susceptible host, that is anyone who is exposed to body fluids containing HIV, hepatitis C virus or hepatitis B virus (for anyone who has not been vaccinated against HBV or who does not have HBVAB)
- A virus with sufficient virulence (infectivity) and dose (numbers) to cause infection
- A portal through which the virus may enter the host, that is, a break in the skin or sharps injury

To prevent cross-infection or transmission of infection only **ONE** of the above conditions needs to be eliminated.

In addition to blood-borne viruses, laboratory work should also be clean so that it is not contaminated with influenza and other respiratory viruses, with fungi such as *Candida* species, or with bacteria such as *Staphylococci*. Although the risk of cross-infection is low from dental laboratory work, it is essential the basic precautions outlined below are followed when handling laboratory work:

- When decontaminating laboratory work, appropriate personal protective equipment must be worn: that is, protective glasses and gloves.

- Develop safe work practices and risk management protocols to reduce the risk of sharps injuries.
- Contaminated work is separated from clean work.
- All items entering the laboratory area should be decontaminated using a suitable agent before they are worked on.

Sending work to the laboratory

- All work going to the laboratory must be rinsed to remove visible blood and saliva, treated with detergent, and rinsed with clean water before being inspected to ensure it is free of blood or visible foreign matter, e.g. denture adhesives.
- The decontaminated item should be placed in a plastic bag, sealed and labelled.
- Laboratory boxes should be wiped with detergent and water prior to being reused to transfer sealed items.
- Some states or health authorities may require additional disinfection of laboratory work. It should be acknowledged that many impression materials will react chemically with disinfectants resulting in a changed product. Some disinfectants, although suitable for use with dental materials, may have occupational hazards associated with their use (e.g. glutaraldehyde). It is extremely difficult to contract infection from a clean item. If not cleanable then barrier protection should be implemented.

Clinic lathe/laboratory areas

Where laboratory items are adjusted in a dedicated area within the surgery, attention needs to be paid to ensure cross contamination does not occur. The area should be prepared and maintained for single patient use procedures. This means fresh pumice, new arbor bands and clean mops, clean brushes and preferably sterilised burs, or at the minimum heat disinfected burs, must be used for each item of work (patients).

Lathe area

Lathes

- Place a bib inside lathe bucket with the plastic surface facing upwards.
- Place pre-measured pumice in denture cup.
- Add tap water to the dry pumice mix with a wooden spatula.
- Place brush / mop inside lathe bucket ready for use.

After use

- Place the used mop / brush in a 'dirty' collection bucket.
- Discard used pumice and container and bib from lathe bucket in waste container.
- Wipe out the lathe bucket if visibly soiled.

Procedure for cleaning/disinfecting lathe mops

- Rinse lathe mops thoroughly to ensure removal of pumice.
- Wash lathe mops in very hot water with detergent. Rinse well in clear water.
- Mops should soak in near boiling or boiling water for five minutes. Boilers may be used.

OR

- Sterilise cleaned mops by placing flat on steriliser tray or in 'toast rack'.

OR

- Items may be washed and disinfected in an instrument washer/thermal disinfectant.
- If necessary treat lathe mops by rinsing in fabric softener which keeps mops soft and deodorised.
- Squeeze excess moisture from mops.
- Place mops on 'toast rack' for drying.
- Place clean mops in tray ready for next use.
- Disintegration of the plastic or leather centre insert may occur. Providing the centre is not over stretched, the mop will generally still fit onto the lathe without the insert.

Procedure for laboratory/lathe area motors, handpieces and burs situated in a clinic lathe area

- Work to be rinsed with detergent and water and rinsed prior to using the handpiece.
- New exam gloves to be worn.
- Pre-sterilised bur to be placed in handpiece.

Cleaning

- Laboratory motor and handpiece to be wiped with a damp cloth impregnated with detergent and water.
- Wipe detergent residue away with a damp wipe.
- Burs are to be cleaned and sterilised after each patient's work completed.

Do **NOT** over wet the handpiece and motor.

Infection control measures for using on-site laboratory facilities and for working in a dental laboratory situation

Specific areas should be designated for incoming work ready for decontamination and laboratory work which should be cleaned and sealed.

Dentists using laboratory facilities for adjustment of appliances, dentures, or any work from the clinic must clean the item before using equipment. The work being adjusted should be treated the same as for incoming work, that is, it should not contaminate new work or clean surfaces. It is imperative to ensure saliva or blood contaminated work does not contaminate new work in preparation or work benches and models.

Incoming items can be cleaned by washing carefully with a detergent. Some items may be cleaned by immersion in an ultrasonic cleaner or in an acid bath. If the incoming laboratory work cannot be adequately cleaned without damaging the work then all procedures carried out on this work should follow protocols for single patient use, for example, fresh pumice, clean mop, and sterilising burs after use on the item.

Cleaning items in an ultrasonic cleaner

- Ultrasonic cleaners must be degassed and regularly tested with the foil test to ensure they are functioning properly.
- Items to be cleaned should be placed in an immersion basket for the required time.
- The time required to clean an item will obviously depend on the amount of contamination present.
- Cleaned items should be rinsed under warm running water and dried before being taken to the laboratory area.
- If the item has been grossly contaminated it may be necessary to change the ultrasonic solution after use.

Cleaning items in an acid bath

An acid bath is a very effective way of cleaning laboratory work. Acids are hazardous materials and must be carefully handled according to the following principles:

- The acid bath is made up of concentrated hydrochloric acid diluted 1:1 (that is, 50mL acid added slowly to 50mL water) placed in a closed glass container. When diluting acid to 1:1 mix, always add acid slowly to water.
- The lid should only be removed for work to be immersed.
- The closed glass container should be kept in a fume cupboard.

- A protective apron, glasses and heavy-duty gloves should be worn.
- Tongs should be used to add dentures and appliances to the acid bath.
- Items should be soaked for a minimum of 60 seconds.
- Work should be rinsed in water following immersion in an acid bath.
- Bicarbonate of soda can be placed around the beaker containing acid, to absorb fumes from the acid.
- Disposal of acid – dilute by 100% with water then flush down the sink with copious amounts of water.

Infection control protocols for the dental laboratory

- Clearly identify areas in laboratory for incoming and outgoing work.
- Hands **must** washed before starting work.
- Technicians **must** develop work practices to isolate contaminated work from clean work; that is, all work must be clean before placed on workbench.
- Old work (repairs, dentures for adjustment/grind in: If suitable for acrylic items and for removal of gross organic debris), items can be soaked in an **acid bath** for a minimum of 60 seconds and then rinsed with detergent/water. If unable to adequately clean items then old items (such as existing dentures requiring repair) need to be processed separately from new work.
- New work must be washed with detergent and water and rinsed in running water.

Management of gutta percha points in endodontics

Gutta percha (GP) is not available in individual unit doses or blister packs like paper points. GP points are not guaranteed nor claimed to be sterile. However, under the current Goods Manufacturing Practice requirements of the Therapeutic Goods Administration (TGA), it can be presumed that a manufacturer uses ingredients, production techniques and packaging to supply these materials as a so-called 'clean packet product'; that is, products that are only minimally contaminated by 'dirt and/or microorganisms, dead or viable'. A number of authors^{1, 2} have found in the majority of instances, the contents of GP containers were sterile, provided these were aseptically opened and handled.

Disinfection of GP points prior to use has been suggested, using a number of different chemical agents. It has been consistently found that a minimum of one-minute immersion in 5.25% sodium hypochlorite was sufficient to sterilise GP cones, and concluded this would be a suitable method for chairside sterilisation.^{1,3} Soaking GP or polymer cones in 5.25% sodium hypochlorite does not appear to adversely affect their surface.⁴ On this basis, soaking GP points in 5.25% sodium hypochlorite for at least one minute can be recommended as a clinical protocol. If a lesser concentration is used the soaking time should be increased.

Once the GP cones have been disinfected, they should be handled to reduce the likelihood of recontamination. Based on the principles of aseptic non-touch technique (ANTT), the disinfected cones can be picked up with tweezers held in non-sterile gloves. If the clinician feels compelled to touch the disinfected GP cones with their hands, they should use sterile gloves.⁵

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Endodontic files

Reamers, files and broaches used in endodontic treatment are single-use and not used for other patients.

For rotary Ni-Ti files, they may be single-use or may be reprocessed a limited number of times (a maximum of three is suggested) using a verified cleaning regime.

The following recommended procedure is based on **Effective Cleaning Protocols for Rotary Nickel-Titanium Files** published in the *Australian Endodontic Journal*.¹

1. Insert files into a scouring sponge soaked in 0.2% chlorhexidine gluconate aqueous solution immediately after use at the chairside;
2. Clean the files using 10 vigorous in-and-out strokes in the sponge;
3. Place the files in a wire mesh basket and immerse in an enzymatic cleaning solution (Empower) for 30 minutes;
4. This is followed by a 15 minute ultrasonification in the enzymatic cleaning solution; and
5. Rinse in running tap water for 20 seconds.

NOTE: Work Health and Safety legislation must be observed to minimise the risk of injury during any procedure involving manual cleaning of sharp instruments.

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Airborne risk reduction

Diseases may be transmitted via the airborne (breathing) route. Airborne dissemination may occur by either airborne droplets or dust particles. Airborne transmission includes aerosols (colloidal particles in the gas) which may be generated during certain procedures, including manual washing of instruments or equipment; ultrasonic cleaners operated without close fitting lids in place; and fast moving equipment such as dental drills and ultrasonic scalars. Microorganisms carried in this way can be widely disbursed by air currents through ventilation or air-conditioning systems. Immunosuppressed patients, for a variety of reasons, are particularly vulnerable to infection caused by organisms spread in this manner.

Some of the principles governing the spread of airborne particles are discussed in *AS 1386.1*.

Airborne particles

Airborne particulate matter may be organic or inorganic, viable or non-viable. Most contaminated control problems concern the total (gross) contamination within the air. Airborne particles range in size from 0.001 μm to several hundred micrometres.

The rate at which aerosolised particles tend to settle out depends on the size and density of the particle. For example, according to Stokes law, in a room 2.4 m high, a particle in the 50 μm range would take less than 60 seconds to settle out while a particle in the 1 μm range would take 15–20 hours to settle out in still air.

Particulate control

The allowable size of an airborne particle at a point within an area depends on the most critical dimensions and tolerances of the process to be performed at that particular point. At the same time, consideration must be given to the quantity of the particles of a given size that may be present at a particular point within the area.

Since a definite relationship exists between the size of a particle and the time in which it may be airborne, as defined by Stokes law, it is most meaningful to discuss airborne particles by quantity of a given size.

To further analyse the level of contamination control required, the source of the contamination should be considered. Basically, this is divided into external and internal sources.

External sources

For any given space, there exists the external influence of gross atmospheric contamination or air pollution which tends to find its way into all areas of the working environment.

The external contamination is brought in primarily through the air-conditioning system which supplies the workplace with outdoor ventilation makeup air. In addition to the airconditioning system, external contamination can infiltrate through doors, windows and cracks within the structure. The contamination introduced to the process is controlled primarily by the type of filtration utilised and the pressurisation of the room.

Internal sources

One of the greatest sources of internal contamination is people themselves. All people continually shed particles (viable and non-viable); the amount can vary from as few as several hundred particles per hour to hundreds of thousands of particles per hour, depending on the individual. Skin is constantly flaking off and generating particles in the 1 μm range and exhaled breath contains large quantities of particles ranging in size from a sub micrometre to several hundred micrometres. Thus, people can be considered the highest contributor of contamination within a typical clean room

Further statistics

Internally generated contamination is also caused through the activity of service equipment within the area necessary to the process. Contamination is generated by products such as pharmaceuticals and solids as carbon and other dusts. Service equipment such as soldering irons, solder, flux instrumentation equipment, cleaning agents, cardboard cartons, etc., must also be considered as possible sources of contamination.

Thermal effects on air circulation patterns should not be overlooked.

It should be stressed that every activity involving friction of surfaces also creates some type of contamination. For example, the simple act of writing with a pencil on a piece of paper generates an aerosol cloud of many thousands of very fine carbon particles. Even the movement of two pieces of metal together generates a certain amount of particulate matter which can be aerosolised to form a very fine metallic dust as an airborne contaminant.

Within any working environment a certain dynamic situation exists in the air.

Movement results from people working, machines in operation, fans blowing, motors rotating, and the like. All these motions impart kinetic energy to the air and cause it to move at random velocities within the space. An example is a person walking down an aisle or hallway, imparting kinetic energy to the air, causing air motion as the gas molecules are compressed in front of the person.

Fine particles caught up in the random current within a room are easily moved from one area of the room to another. This transfer of contamination via random air currents from one part of the room to another is known as cross-contamination and is a significant contributor to the contamination level at the worksite. A resulting contamination build-up occurs within the space and reaches a plateau or steady state condition. A plateau count of 0.5 µm particles and larger would range anywhere from several thousand to several million particles in a typical manufacturing environment. During off-hours or lunch breaks, a noticeable reduction in the contamination level will occur.

In the dental surgery the most common cause of airborne aerosols is the high speed air rotor handpiece and ultrasonic scaler. The aerosol produced may be contaminated with bacteria from saliva or viruses from the patient's blood.

Microdroplets about two to five microns in diameter are expelled from the respiratory tract of individuals by coughing, sneezing, singing, laughing or shouting. These microdroplets may contain viruses which cause upper respiratory tract infections, bacteria such as *Staphylococcus aureus* as well as mycobacteria.

S. aureus is present on the skin and in the noses of approximately 30–50% of the general population.

Nasal secretions contain a large number of bacteria which will contaminate the hands. Shedding of skin releases these bacteria both into the air and eventually they settle in dust. In addition, the bacteria are shed from person to person by skin contact.

In many instances the strains of *Mycobacterium tuberculosis* are resistant to first and second-line anti-tuberculous agents, and in some instances the mycobacteria are resistant to all known agents, making a cure almost impossible in these patients. Many cases of early infection may remain undiagnosed for many months. It is possible for these infected patients to attend dentists for routine treatment.

Airborne invasive fungal infections are an increasing problem for patients suffering from immunodeficiencies. These organisms may cause severe systemic infections. In hospitals, opportunistic fungi such as *Aspergillus fumigatus*, *Candida albicans*, and other species have all been isolated from air samples from damp areas where equipment is stored in moist cardboard boxes.

In the dental surgery, all packaged and wrapped sterile instruments should be stored in a clean, dry place to ensure sterility is maintained and packaging is not damaged by contact with sharp objects.

Semi-critical instruments for routine non-invasive dental procedures (e.g. amalgam pluggers and excavators) should be stored to protect from environmental contamination.

In the dental surgery the major source of environmental contamination is airborne bacteria and viruses which settle on instruments, bracket tables, open drawers, etc.

An efficient way to protect sterilised instruments from environmental contamination is to bag them prior to autoclaving and store in the unopened bag. This applies to instruments which must be sterile at the time of use. The same approach and management can also be applied to semi-critical instruments which only need to be sterilised in between patients.

In addition, it is recommended cartridges of local anaesthetic packed in blister packs only be opened at the time of use for each individual cartridge. Also, cartridges of local anaesthetic packed in bubble packs are clean but not sterile.

Cleaning and sterilising high and low speed dental handpieces for restorative dentistry

The evidence base for cross-infection in dental practice from classic studies conducted in the mid 1970s demonstrated that risks can be minimised by appropriate reprocessing and sterilisation of used instruments, including dental handpieces.¹⁻⁴ Handpieces have complex internal structures that require regular lubrication. The protocols for handpiece reprocessing should be broken down into separate elements.

Handpiece tubing and handpiece couplings for high speed handpieces cannot be processed through thermal disinfectors or steam sterilisers. These contain LEDs and electrical components which are damaged by exposure to water or steam. The exterior of handpiece couplings and handpiece tubing is cleaned by wiping down.

Contamination of the external surfaces of handpieces

During normal operation, the external surfaces of dental handpieces used in restorative dentistry usually become contaminated with patient saliva and blood. Exterior surfaces of handpieces and their supply tubing must be thoroughly cleaned immediately after use, before lubrication and sterilisation. If blood remains for a period of time on the external or internal surfaces of handpieces, it can clot and become adherent, making it difficult to remove. Blood can also cause surface discolouration, staining and rusting.

Ideally, when the used bur is removed and the handpiece disconnected from the dental unit, the outside of the handpiece should be cleaned with detergent and water, or with an impregnated wipe, such as one containing detergent and alcohol, or a professional non-corrosive TGA approved disinfectant. If running water is used during manual cleaning of dental handpieces, a temperature of < 38°C (tepid or lukewarm) is recommended as this is optimal for making both protein- and lipid-rich materials easier to remove from the surface. When rinsing under running water in a sink, using demineralised water for the final rinse reduces the likelihood of spotting on the surface during sterilising. Under running water, a soft to medium brush will ensure a clean surface is obtained.

Certain cleaning methods must be avoided. Never immerse handpieces in disinfectant solutions, or attempt to clean them in an ultrasonic cleaner. Never use highly acidic (low pH) water or aqueous solutions. These will degrade the surface of the handpiece, particularly titanium surfaces which are highly sensitive to certain acids. Never use organic solvents such as benzene or thinners on a handpiece. Avoid using abrasive cleaning agents and wire brushes as these will scratch the surface.

A number of modern dental handpieces are designed so they can be safely processed through and dried in a TGA registered thermal disinfectant (instrument washer).

These handpieces will be labelled by the manufacturer, for example, the NSK T-Max and S-Max handpieces. The acceptable pH range for processing handpieces in an instrument washer is between 2.5 and 10.5 pH. It is essential to activate the rinse cycle of the thermal disinfectant to remove all traces of detergent. After washing with a thermal disinfectant and prior to lubrication, it is important to thoroughly dry the handpiece until all internal moisture is removed, before proceeding to lubrication, since moisture remaining inside the handpiece can reduce the effect of lubrication and lead to corrosion. This means the drying step of the thermal disinfectant sequence must be activated. If handpieces are removed from the thermal disinfectant not completely dry, then dry them manually (e.g. using a lint free cloth) and allow them to stand vertically to allow water to flow out under gravity from the inner tubing, before proceeding to lubricate them.

Contamination of internal surfaces of handpieces

Internal surfaces of handpieces can be contaminated by bacteria in the dental unit waterlines and by aspiration of material from the patient's mouth if anti-retraction systems are missing or have malfunctioned. This problem was first shown in detail in the late 1960s.^{5,6} Studies of dental handpieces not sterilised between patients, and out of use for more than 12 months have shown the persistence of bacteria. Direct contamination of the internal aspects of handpieces following their use on patients has also been shown.⁷

When handpieces generate aerosols and droplets a mixture of both patient-derived material and microorganisms derived from biofilms form in dental handpiece tubing. These biofilms are comprised primarily of waterborne bacteria, but can include oral bacteria if systems are not in place to prevent the retraction of a patient's fluids when using the handpiece.

Dental unit waterline biofilm is a reservoir of microbial contamination of the water spray lines of both high and low speed handpieces. Key pathogens which have been found in this biofilm include *Legionella pneumophila* (causing Legionnaire's disease and Pontiac fever), *Pseudomonas aeruginosa* (infects soft tissue wounds and causes pneumonia), and non-tuberculous mycobacteria (causes tuberculosis-like diseases). There is evidence all these pathogens can be transmitted in a dental practice by handpiece-generated aerosols and from irrigant water.

Dental handpieces aerosolize patient saliva and generate large amounts of splatter and droplets and can transmit viral influenza, chicken pox and other viral diseases. Dental handpiece aerosols do not transmit HIV since this requires blood to blood contact, and the virus is partly inactivated by salivary enzymes.

Water treatments including the use of chemical additives (such as peroxides and silver compounds) can reduce the rate of accumulation of bacterial biofilms in the waterlines which feed handpieces. Unless sterile water is used from the time a new dental chair is installed, it is almost impossible to stop the rapid formation of these biofilms. This explains why waterlines to dental handpieces should be flushed for a minimum of two minutes at the start of the day and for 30 seconds between patients.

Heavy deposits of biofilm will make the exit water cloudy, and portions of the biofilm can break off and block the water spray nozzles. Should these blockages occur and the spray nozzles become clogged, the water spray will not exit evenly from them. To clean the nozzles, a cleaning wire can be used to carefully dislodge material from the nozzle jets. It is important not to forcibly insert a cleaning wire into the nozzle as this could damage it, causing the spray to be directed away from the bur, which lowers the efficiency of the water spray in cooling.

In most handpieces, a water non-retraction valve is integrated into the coupling, which shuts off the water flow directly at the handpiece head to prevent fluids infiltrating the water line.

In addition, certain handpieces have anti-retraction systems in the turbine head. For example, NSK handpieces have a 'Clean-Head' system which prevents material from the mouth entering the handpiece head. The ports for this are located beside the water spray outlets of the air turbine. After each patient's treatment the system is readily cleaned by running the handpiece with its head submerged into half a cup of clean water in an intermittent pattern (running for three times for 2 to 3 seconds each time, followed by a short break). This is an example of a particular handpiece which is designed to be operated for short bursts when immersed in water. This must not be done for other handpieces as damage will likely result.

Cleaning and lubrication

All air driven dental handpieces must be cleaned and lubricated in accordance with the manufacturer's instructions, before being cleaned and sterilised after each patient. Similarly, ultrasonic scaler handpieces or inserts must also be sterilised between patients. Lubrication must occur after cleaning or thermal disinfection, and thus before steam sterilisation. The lubricants used are designed to withstand autoclaving. Prior to sterilisation of a dental handpiece, the exterior surfaces must be thoroughly cleaned to remove traces of saliva and blood, and then their internal aspects cleaned and lubricated, according to the manufacturer's instructions. This internal cleaning and lubrication can be completed using either an aerosol pressure pack spray can or an automated lubricating device.

Automated cleaning and lubrication systems

Whether using an automated system or a pressure pack, be sure to use the right adaptor for each type and brand of handpiece. Similar types of handpiece adaptors are used in thermal disinfectors/instrument washers.

There are many advantages to using a purpose-built automatic handpiece cleaning and lubricating system. These systems control the dose of oil and detergents based on which handpiece type is being treated. For some low speed handpieces extra lubricant solution and lubricating time is required compared to air turbine handpieces. For speed increasing or speed reducing handpieces even more time is required because of their complex internal gearing systems. After dosing the lubricant, the handpiece is run in purge or flush mode using compressed air to expel excess material, which prevents the problem of lubricants affecting steam quality during steriliser cycles.

Compared to pressure packs, the cost of lubrication is less with an automated system as there is no waste and there is an economy of scale from using a larger reservoir of lubricant oil. They also use a lighter grade of lubricant than pressure packs, which provides better penetration into bearings and thus better lubrication and a longer life for handpieces and their internal components. Overall, automated systems are not only faster, they are always consistent in what they achieve.

Automated systems create less mess as they dose the lubricant precisely and use various design features to contain, trap and absorb any spray mist generated in the lubrication process.

Some systems also include chuck cleaning functions.

Manual cleaning

If lubrication is carried out manually using a pressure pack, care is required to apply the oil for the correct length of time. Staff must ensure the correct application time is used, since excessive lubricants will carry over into the steam sterilisation cycle which can compromise the sterilisation process. Of particular concern is the combination of manual lubrication with using a steam steriliser where the steam is condensed back into water and re-used for subsequent cycles. The accumulation of excessive lubricants contaminates the reservoir water, resulting in over-dry, super-heated steam which is unsuitable for sterilising. In such sterilisers, the deionised, demineralised or distilled water in the reservoir of the sterilisers should be replaced weekly after thoroughly flushing out the reservoir to remove traces of lubricants.

If a dedicated handpiece cleaning system is not used, the following method should be followed to reduce the problems caused by lubricant residue.

Prior to steam sterilisation:

- Remove any burs from the chuck before removing the handpiece from the coupling on the dental chair. Some brands of air turbine handpiece require a blank bur to be placed in the chuck during cleaning to prevent contamination of and damage to the handpiece bearings during lubrication;
- Clean the outside of the handpiece, taking care to wipe down all clinical contact surfaces. Do not submerge the handpiece in water or any other solution when rinsing away detergents;
- Lubricate the handpiece with pressurised oil from the pressure pack for the recommended period. When applying lubricating spray, hold the handpiece firmly to prevent the handpiece from slipping out of the hand due to spray pressure. The spray can should be held upright to ensure a smooth flow of propellant gas. To prevent mist spray from escaping into the environment of the sterilising room, use an absorbent cloth to hold the handpiece and trap excess lubricant, or a purpose-made spray mist absorber. It is important to spray for the precise time stated by the manufacturer (e.g. 1 or 2 seconds) and to check for lubricant being expelled from the handpiece head;
- Check for debris in the expelled lubricant. If the lubricating oil is not running cleanly, then repeat the application from the pressure pack until the internal channels of the handpiece are clean and free of visible residue;
- Clean off any excess oil from the exterior of the handpiece, and place it to drain vertically for several minutes over a disposable paper towel;
- Sterilise in a steam steriliser. This can be done either unwrapped or wrapped. If wrapped, ensure a longer cycle time is used in the steriliser to allow for air removal and steam penetration through the pouch being used. If wrapped, the steam steriliser must use a drying cycle;
- At the start of each clinical procedure, run the air turbine handpiece briefly over a piece of gauze to clear excess lubricant before using it in the mouth (note this step is not required for dosed automated lubrication systems which have run or purge cycles at the end of the lubricating process); and
- Clean the chuck weekly to ensure its friction grip on burs remains strong thus preventing them from being accidentally released whilst the handpiece is in operation. Typically, this is done by applying lubricant spray directly through the bur insertion hole of the chuck for 1 to 2 seconds.

Sterilisation protocols

Steam sterilisation has been used for over 40 years for handpiece sterilisation. Using steam sterilisation at 134°C for 3 to 4 minutes has been shown to be effective even when bacteria and fungi were deliberately forced into brand new handpiece.⁷

The connection for a high speed handpiece typically contains a light guide for fibre optic illumination and three pipes – the smallest for water spray; a medium pipe to drive air to the turbine; and a large pipe for the turbine exhaust. In a Midwest 4 hole connector, the water and air for the spray are separated, giving four pipes rather than three. These pipes are all classed as Type A hollow items (i.e. the ratio of the length of the pipe to its diameter is more than 5:1).

It is recommended to use a pre-vacuum steam sterilisation cycle (e.g. B cycle) wherever possible to ensure reliable air removal and steam penetration can be achieved into these areas. Most handpiece manufacturers recommend a pre-vacuum cycle (Class B or Class S) for sterilisation of handpieces.

Handpieces will be labelled according to their ability to tolerate steam sterilisation. Typical cycles employ holding times of 134°C for 3.5 minutes; handpieces will be labelled to indicate this or will be labelled to indicate it can tolerate autoclaving up to a maximum of 135°C. Recommended holding times at the sterilising conditions include 20 minutes at 121°C; 15 minutes at 132 °C; or 3 minutes at 134°C (based on *EN13060 4.6.3 / EN ISO17665-1*). Added to [these times will be the required times for air removal and post-sterilisation drying as necessary. Remove the handpieces from the steam steriliser chamber as soon as the cycle has finished.

For dental handpieces, the validity of sterilisation methods other than steam sterilisation, such as dry heat, plasma sterilisation or ethylene oxide gas, has not been confirmed, and so these methods must not be used. The long exposure time and high temperature of dry heat sterilisation would compromise the lubricating properties of the oils used, and could affect the integrity of the air turbine rotor.

Regular high and low speed handpieces used for restorative dentistry are classed as semi-critical, so these may be wrapped or left unwrapped, according to local preferences. If it is decided to wrap handpieces, for example, using paper-plastic pouches, it is important to place just one handpiece in each pouch before sealing the pouch. Do not place other items in the same pouch, to avoid possible discolouration and damage to the handpiece from chemical reactions with materials or residues from these other instruments.

Storage of sterilised handpieces

After sterilising, dental handpieces must be stored to prevent environmental contamination from clinical work or instrument cleaning. At the end of the steriliser cycle, the sterilised handpieces should be dry. If using pouches, processing through a B or an S cycle should produce a fully dry package. A wrapped handpiece must not be processed through an N or gravity displacement cycle; these will not give adequate air removal and will leave the pack wet and therefore prone to recontamination when it touches any surface.

Whether wrapped or unwrapped, this can typically be achieved by placing them in a non-absorbent tray in a drawer or closed cupboard which is away from the contaminated working zone where patient treatment is undertaken. Ideally, handpieces should be stored with the head higher than the body (head up position).

Wrapped handpieces should be kept under normal room temperature and humidity in a well ventilated area, out of direct sunlight, so that premature degradation of the pouch does not occur. The air in the storage area should be free from dust, salt and sulphur.

To prevent contamination by splashed and splattered patient fluids, handpieces should not be fitted to the dental unit until the start of a procedure where they will be used. In other words, the handpiece should remain in the autoclave pouch until required for use. If unused or not planned to be used, it should not be left sitting attached to the dental unit during other procedures since it can become contaminated – and therefore will need to be cleaned, lubricated and re-sterilised even if not actually used on that patient.

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Infection control issues with triple syringe tips

A number of high end dental chairs have bespoke triple syringe designs with tips designed for reprocessing including steam sterilisation. However, many dental chairs are fitted with a generic or DCI/A-dec type triple syringe for which both metal reusable tips and disposable plastic tips are readily available. Thus, the question arises as to which of these two options for the DCI/A-dec type triple syringe is better.

For metal reusable triple syringe tips, ultrasonic cleaning will have low effectiveness as these hollow items have fine, long lumens. These features pose particular challenges for air removal and steam penetration during steam sterilisation, requiring a pre-vacuum cycle to completely remove air from the lumens and ensure the penetration of steam. They cannot be sterilised in a downward displacement steam steriliser (N cycle).

It has been known for many years that internal fine air and water channels of a triple syringe tip are difficult to clean, and become contaminated during use.¹⁻⁵ Studies show that cleaning and sterilising methods used for reusable metal triple syringe tips are inadequate for achieving removal of bioburden.^{1,2,6,7}

There have been two detailed studies of the issues associated with reprocessing of metal triple syringe tips. The first of these, published in 1999, examined the lumen surfaces of used and unused metal tips of air/water syringes using both light and scanning electron microscopy. The internal surfaces of metal tips were found to be rough, enhancing the accumulation of both mineral deposits and bioburden. A survey of both patients and dentists regarding the choice of reusable versus disposable triple syringes found disposable tips were more acceptable in clinical use than metal tips.⁶

The second study, published in 2014, also evaluated the efficacy of cleaning and sterilising metal triple syringe tips, and documented corrosion and contaminant build-up in these tips, in the form of either corrosive breakdown, with subsequent pitting of the metallic surface, or chemical contaminant build-up within the lumen, or both.⁷ This problem was attributed in part to retention of water in the metal tips due to capillary action, leading to stagnation and corrosion.

The second study also measured bacterial contamination of disposable tips versus reusable tips after routine use and sterilisation using microbial culture methods after use. Non-disposable syringe tips had significantly greater bacterial contamination than single-use disposable tips. The investigators also explored whether there was any benefit from flushing the metal syringe tips with water prior to sterilisation, and did not find any significant benefit. The results confirmed those from earlier studies by showing that sterilisation of used metal non-disposable air/water syringe tips is not completely effective.

The authors concluded there may be a lower risk of cross-infection from the use of plastic disposable air/water syringe tips, rather than non-disposable metal ones.

In summary, accumulation of internal bioburden over time could potentially compromise sterilisation procedures for metal triple syringe tips. Because of this problem, and the need to use pre-vacuum sterilising cycles to ensure adequate air removal and steam penetration, many clinics have moved to using disposable plastic triple syringe tips, as these are more convenient to use and eliminate concerns about inadequate cleaning and sterilisation.

A final point is that any triple syringe tips labelled as single 'one patient' use must not be reprocessed and reused on another patient, but must be discarded after use. Likewise, regardless of the type of tip used, it is still recommended that the lines which feed the air/water triple syringe are flushed after each patient appointment. Not only will this help dislodge potentially infectious foreign material from the lumens of the tips, it will also reduce biofilm accumulation in the waterlines.

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Recognising common mistakes in the sterilising room

In 2015 attention has been directed to breaches in infection control in certain dental practices in NSW and to the improper practise of dentistry by non-registered persons in Victoria. The issue of risk to the public from improperly reprocessed dental instruments attracts adverse publicity for the dental profession and lowers the historically high level of trust which dental patients have had for their dental practitioner.

Getting the best performance from an ultrasonic cleaner

For maximum efficiency, items should be separated in the chamber to avoid edges touching, which prevents access to the shear force which dislodge debris. Instruments placed into a cassette are typically spaced apart for this very reason. As the debris is loosened from instruments and falls off into the solution, the efficiency of the cleaning process is reduced. This is why the water in an ultrasonic cleaner should be changed at least twice daily (i.e. whenever it becomes cloudy). As ultrasonic cleaners do not kill large numbers of microorganisms, items need a very thorough rinsing after removal from the chamber. In addition, the chamber of the ultrasonic cleaner must be left clean, empty and dry at the end of the day so that biofilm does not develop on the chamber walls overnight.

While the aluminium foil test is a useful measure of the function of the ultrasonic transducer, it is important to perform this daily test after additive has been placed in the water, and the water fully degassed, to avoid false negative results.

Correct segregation of items

It is essential any items labelled or designated as single 'one patient' use items are not reprocessed, but instead are disposed of immediately after use and not reused. Each practice should check its protocols for reprocessing burs and nickel titanium (NiTi) rotary files, and ensure hand endodontic files, reamers and broaches are disposed of immediately after use – ideally into a sharps bin located at the chairside rather than being carried into the sterilising room. Any burs which are intended for reuse must still have effective cutting abilities and also be free of rust and corrosion.

Likewise, it is important to check that reprocessing of instruments is in accordance with the Spaulding classification (critical, semi-critical and non-critical) and **AS/NZS 4815** or **AS/NZS 4187**. Instruments such as dental forceps, elevators, flap retractors and surgical burs, instruments sets used in the placement of implants, and surgical dental handpieces must all be sterile at the point of use, and thus must be wrapped prior to sterilisation and kept stored in bags until required. All these items should have a batch code.

For wrapped items, it is important the method of sealing is appropriate, i.e. it does not compromise integrity and has sufficient longevity, for example, using steriliser tape or heat sealing, but not staples.

Checking the efficiency of the instrument cleaning process

A common problem in sterilising rooms is a lack of sufficient lighting at the level of the bench, which impedes the ability to check items after cleaning, and increases the likelihood of staff sustaining sharps injuries when packaging items. It is often worthwhile to add in a strip of cold white LED lights to increase local lighting levels in the instrument inspection and packaging area. Also available are LED benchtop lights with built in magnification which are well suited to inspecting instruments, burs and rotary NiTi files after cleaning.

If there are recurring problems with items coming out from mechanical cleaning with visible residue, attention should be paid to the pre-cleaning stages. Dental instruments and devices contaminated with blood, saliva, cements, varnishes and other materials which can dry and harden should be treated appropriately to prevent these substances drying on them. A simple way of doing this is to wipe debris from instruments at the chairside onto a piece of sponge using a one-handed method. It can also be useful to soak items in water and detergent if they are not cleaned immediately, rather than leaving them in a dry state.

Correct cycle selection

All wrapped items must go through a cycle which has an effective drying stage, so they leave the chamber dry. This can be an S or B cycle, but never an N cycle. It is very useful to have the hard copy of the steam steriliser's instructions available in the sterilising room to ensure staff have ready access to the manufacturer's instructions on cycle selection. This is particularly important for the content of any specified (S) cycles.

When choosing cycles for mixed loads of solid instruments and hollow items (such as surgical suction tips, metal triplex tips, or dental handpieces) do not use a gravity displacement cycle, since this is unlikely to give effective air removal.

The chamber of the steam steriliser must be loaded correctly and not overcrowded or overfilled. Items must not touch the chamber walls. Space is required between packages to allow them to expand and contract during pre-vacuum cycles.

Water quality

Water for steam sterilisers must be treated to remove ions and other inorganic components. Typically, this is done using reverse osmosis (using deioniser cartridges) or by distillation. If by the former, the cartridges have a fixed 'use by date' and must be replaced periodically.

If distilled water is produced on site, there must be periodic (weekly or monthly as appropriate) acid treatments of the heating elements to remove deposits of calcium, magnesium, aluminium and other compounds.

Storage of packages

Careful storage is necessary to minimise the chance of damage to packages during their storage. In addition, all packages of sterilised items should be checked for damage before being opened and used in patient treatment.

Packages should not be stored near sterilising room sinks to prevent them being splashed with water. The storage area for packages should be located away from the instrument cleaning area.

Appropriate records

There must be a steriliser cycle record book for each steam steriliser, recording details when the cycle is loaded, and again with additional data on cycle performance at the end of each steriliser cycle.

As well as individual cycle records, records for Installation Qualification, Operational Qualification and for Performance Qualification need to be kept. These records will build-up over time, as leak rate and air removal test results are recorded for pre-vacuum sterilisers, and calibration of thermocouples is undertaken each year.

The cycle records should include hard copy printouts but not chemical indicator strips as these are not designed for archiving and the quality of the colour change results over time cannot be assured. Instead, record the chemical indicator strip result, but discard the strips. This principle applies for indicators inside packages as well as special purpose indicators such as Bowie-Dick tests and Helix tests.

It is essential that both dental practitioners and clinical support staff know how to interpret the types of chemical indicators used inside packages, so they can recognise a failed outcome and not use the instruments.

Recognising failed cycles has been a problem in private and public dental practices across Australia, and is perhaps the greatest area where improvements can be made.

Likewise, all staff should know how to check the integrity of bagged or wrapped items before use, looking for dampness, seal breaches, punctures, tears and other defects in the packaging which compromise the sterility of the contents. This information should be written into the practice's infection control manual so it is available for reference and can be used to train new staff.

Sterilising hollow and porous items

In selecting the appropriate steam sterilising cycle for different items, it is important to appreciate that items which have long or narrow internal cavities provide a greater challenge to air removal and steam penetration. Steam contacts and sterilises only the external surfaces of solid instruments. In contrast, hollow items with internal cavities have both inner and outer surfaces to be sterilised. The inner surfaces of these cavities are not only difficult to clean, they also pose a challenge for removing air to enable access to steam.

Solid items are non-porous items which do not absorb fluids, and which lack hollows or other characteristics that would hinder the penetration of steam (e.g. excavators, curettes, and probes). Solid items such as kidney dishes and bowls, despite their shape, are not classified as a hollow object.

Porous items are those where the item can absorb fluids (e.g. textile drapes, surgical gowns, gauze packs).

Hollow items are divided into two categories in *AS/NZS 4815 Hollow load type A*, where the ratio of the length of the internal cavity to its diameter is more than 5:1; and *Hollow load type B*, where the ratio of the length of the cavity to the internal diameter < 5 but > 1 .

The distinction between type A and type B hollow items is also found in EN 13060, which differentiates further between items open at one end (such as air turbine handpieces which have multiple internal tubes) and items which are open at both ends (such as tubing or suction tips). It also considers the total length of the item. Under this European norm, a type B hollow item is defined as either having:

- (a) a single ended open space where the ratio of the length to the diameter of the cavity is ≥ 1 and ≤ 5 and where the diameter is ≥ 5 mm, or
- (b) an double ended open space where the ratio of length to diameter of the cavity is ≥ 2 and ≤ 10 and where the diameter is ≥ 5 mm.

Under *EN 13060*, a type A hollow item has either

- (a) a single ended open space where the ratio of the length to the diameter of the cavity is ≥ 1 and ≤ 750 and where the length of the cavity is not greater than 1,500 mm, or
- (b) a double ended open space where the ratio of the length to the diameter of the cavity is ≥ 2 and $\leq 1,500$ mm and where the length of the cavity is not 3,000 mm and which is not hollow load B.

Type A hollow items provide a greater challenge to air removal and steam penetration than type B hollow items. Many hollow items used in clinical practice are type A, including air turbine handpieces. This point underpins recommendations that these be processed using a steam steriliser with a prevacuum cycle (either B or S) with multiple vacuum pulses.

It is important to follow precisely the manufacturer's written instructions regarding the recommended sterilisation protocols for specific items. If these instructions are not explicit regarding whether the item is a solid item or a type A or type B hollow item, the above definitions can readily be applied to classify the item correctly.

Common examples of the classification of items are given in the following table:

Hollow items	Porous items
Surgical suction/aspirator tips	Linen drapes and surgical gowns
Surgical suction tubing	Packs of gauze squares
Air turbine high speed handpieces	Packs of cotton rolls
Air turbine low speed handpieces	Packs of cotton pellets

Reusable metal triplex syringe tips are a type A hollow item, which pose additional challenges for effective cleaning and sterilisation. Refer to the section on triple syringe tips in this guide for a discussion of these problems and the recommended solutions.

The identification of an item to be processed relates directly to the choice of steam sterilising process.

EN 13060 describes three different steam sterilisation cycle types.

Type N process: The letter 'N' stands for 'None', from 'none wrapped' and 'none hollow'. A steam steriliser which can only run N cycles (e.g. a gravity displacement steriliser) cannot be used to sterilise hollow, porous or wrapped items. It can only be used on unwrapped solid items.

Type S process: The letter 'S' stands for 'Specified' products. In these steriliser cycles the manufacturer of the steriliser has to specify what can and cannot be sterilised in this type S process. The sterilisation of products is specified by the manufacturer of the steriliser. Typically this may include a mix of unwrapped solid items and at least one of the following: porous items, type A hollow items, type B hollow items, and single wrapped items.

Type B process: This allows for sterilisation of all wrapped or non-wrapped, solid, hollow, or porous items.