
INFECTION PREVENTION AND CONTROL MANUAL

9.1 Cleaning Disinfection and Sterilisation of Reusable Medical Equipment

DEFINITIONS

CLEANING

The removal of soil and reduction in the number of microorganisms from a surface by a process such as washing in detergent without prior processing.

DISINFECTION:

The inactivation of non-spore forming organisms using either heat and water (thermal) or by chemical means.

STERILISATION

A validated process that is used to render a product free of all forms of viable microorganisms.

In a sterilisation process, the nature of microbial death is described by an exponential function. Therefore the presence of micro-organisms on any individual item can be expressed in terms of probability. While this can be reduced to a very *low* number, it can never be reduced to zero.

RATIONALE

Inadequate cleaning has resulted in the transmission of infection including Hepatitis B, HIV and Hepatitis C. The time required for any method of disinfection or sterilisation to be effective depends upon the number of organisms to be destroyed. It is important to reduce the number of organisms to a minimum before exposing the equipment to the sterilising or disinfecting process. Thus fastidious cleaning is the single most important factor in achieving high levels of disinfection or sterilisation of medical equipment. In accordance with Human Services Victoria requirements, all sterilising units will comply with the requirements of AS/NZS 4187 - 2003 for the provision of sterilised goods for patient use.

CLASSIFICATION OF RISK

For assessment of associated risk the classification of patient equipment into three different categories can be used to assess the level of cleaning, disinfection or sterilisation required.

Level of Risk	Application	Process	Storage	Example
Critical	Entry or penetration into sterile tissue, cavity or blood stream	Sterilisation by steam under pressure, or a minimum of an automated low-temperature or other high level chemical sterilant system or ethylene oxide sterilisation (i.e. must be sterile) Special conditions apply to CJD (For further information on CJD, refer to Infection Control Guidelines for the prevention of transmission of infectious diseases in the health care setting, Jan 2004: sections 17 & 31)	Sterility must be maintained: - packaged items should be allowed to dry before removal from the steriliser; - the integrity of the wrap must be maintained, wraps should act as an effective biobarrier during storage, store to protect from environmental contamination, unpacked sterile items must be used immediately.	Instruments used in invasive surgical procedures eg. Arthroscopes, cardiac catheters, surgical instruments. Respiratory or anaesthetic equipment (eg endotracheal, laryngeal and pharyngeal tubes and suckers)
Semi Critical	Contact with intact nonsterile mucosa or non-intact skin.	Heat-tolerant items preferably steam sterilised where possible, or a minimum of thermal disinfection If the equipment will not tolerate steam sterilisation use, use low-temperature automated chemical sterilant systems or a minimum of high-level chemical disinfection	Store to protect from environmental contamination.	Respiratory or anaesthetic equipment (eg laryngoscope blades, temperature probes, reusable nebulisers). Fibre optic flexible scopes (eg. Sigmoidoscopes gastroscopes colonoscopes bronchoscopes), invasive ultrasound probes
Non-Critical	Contact with intact skin	Clean as necessary with detergent and water. If decontamination is required, disinfect with a compatible low- or intermediate-level instrument grade disinfectant after cleaning	Store in a clean, dry place	Bed pan, EKG leads, Beds, Transport Trolleys BP cuffs, Oral Thermometers, non invasive ultrasound probes and acupuncture devices

CLEANING

Before sterilisation or disinfection all equipment must be thoroughly cleaned because organic residue may prevent the disinfectant or sterilant from contacting the item being processed and may also bind and inactivate chemical disinfectants.

If an item cannot be cleaned it cannot be disinfected or sterilised.

Good cleaning and disinfection practices involve the following:

- 1.** Initial clean: before returning used items intended for reuse to the sterilising department gross soil must be removed from instruments and equipment as close to the point of use, as soon as possible. Soil should not be allowed to dry onto instruments before cleaning.
- 2.** Detergent and water are generally sufficient for routine cleaning. Abrasive cleaners (e.g. steel wool, abrasive cleaning powders and pastes) must not be used as they may damage the surface of instruments or leave residues.
- 3.** Enzymatic cleaners are hazardous and should not be used for routine cleaning. They should only be used for fiberoptic instruments and accessories and where debris has congealed on to items and cannot be removed by routine cleaning. Staff using enzymatic cleaners should be made aware of associated hazards and material safety data sheets should be displayed
- 4.** The cleaning area must be dedicated for that purpose only with consideration given to directed workflow.
- 5.** Disassemble: allows physical removal of particulate matter and thorough cleaning
- 6.** Cleaning: Thoroughly clean all components with a suitable detergent using a brush if necessary. Thorough cleaning will substantially reduce the microbial load.
- 7.** Ultrasonic cleaners can be used to assist with the cleaning of jointed and serrated stainless steel instruments. They operate by subjecting instruments to high frequency, high energy sound waves, causing soil to be dislodged from instruments, or held in suspension, or sufficiently loosened, to be removed during the rinsing process – ultrasonic cleaners clean but they do not disinfect instruments.
- 8.** Standard precautions must be followed during the cleaning procedure. Use techniques designed to avoid generation of aerosols

PROCEDURE

1. Sterilising Services Units, and other areas undertaking sterilisation and chemical disinfection (eg Formula Room, Podiatry, Dental, Endoscopy, Cardiology Departments) will develop and maintain procedure manuals and practices that reflect compliance with AS/NZS 4187-2003 (Clause 8.2)
2. Records will be maintained of all sterilisation / chemical disinfection processes as required by the standard. AS/NZS 4187-2003 (Clause 8.5 & 8.6)
3. SSD staff will receive ongoing education in matters related to specific work practices related to compliance with AS/NZS 4187-2003 (Clause 8.4).
4. An audit program will be maintained by all Sterilising Units to monitor compliance with AS/NZS 4187-2003 (Clause 8.12).
5. Where chemical disinfection (eg glutaraldehyde/OPA) is employed all safety and monitoring requirements will be observed as described in AS/NZS 4187-2003 and WorkSafe Australia.
6. Appropriate protective equipment will be available to all staff working in areas where sterilisation and/or chemical disinfection is performed.
7. Tests shall be carried out regularly to monitor and test water used for suitability and quality and to maintain records as required by AS 4187/NZS – 2003 (Clause 2.1).
8. Calibration and performance testing and maintenance of sterilisers, glutaraldehyde fume cabinets and associated equipment shall be performed and records maintained by engineering as per the relevant Australian Standards requirements. Departments should have a copy of maintenance records on site and their particular equipment.

REFERENCES:

Australian/New Zealand Standard AS/NZS 4187 2003-Code of Practice for Cleaning, Disinfecting and Sterilising Reusable Medical and Surgical Instruments and Equipment and Maintenance of Associated Environments in Health Care Facilities. Standards Australia 2003.

Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Healthcare Setting. Australian Department of Health and Ageing, 2004.

INFECTION PREVENTION CONTROL MANUAL

9.2 Endoscope Cleaning/Disinfection and monitoring.

RATIONALE

This guideline is mainly derived from **AS 4187-2003** and covers the general principles that should be followed for cleaning and disinfection of all endoscopic instruments. Specific procedures for the cleaning and disinfection of endoscopes used in Gastroenterology and Respiratory Units should be followed as per **GENCA Guidelines 2nd Edition-2003**. Cleaning instructions from the instrument manufacturer should also be consulted.

Single use items will not be processed.

Level of Processing Required For Specific Items and Procedures

Level of Risk	Application	Process	Storage	Example
Critical	Entry or penetration into sterile site (tissue, cavity or blood stream)	Sterilisation by steam under pressure if instruments withstand heat or alternative accepted methods of sterilisation (eg. Ethylene oxide, or automated chemical sterilant)	Sterility must be maintained: - packaged items allowed to dry before removal from steriliser, integrity of the wrap must be maintained, store to protect from environmental contamination	Instruments used in invasive surgical procedures eg. Arthroscopes laparoscopes, ERCP equipment, rigid & flexible bronchoscopes, cystoscopes, hysteroscopes, surgical instruments, including reusable biopsy forceps, snares and accessories used with rigid and flexible endoscopes.
Semi Critical	Contact with intact nonsterile mucosa or non-intact skin.	Sterilisation by steam under pressure. If equipment will not tolerate heat, use low-temperature automated chemical sterilant systems (eg. Ethylene oxide, peracetic acid, hydrogen peroxide) or a minimum of high- level chemical disinfection (eg 2% glutaraldehyde, OPA)	Store to protect from environmental contamination	Fibre optic flexible endoscopes, eg. sigmoidoscopes, gastroscopes, colonoscopes bronchoscopes

Adapted from Table 16.1 Part 3 Australian Government Department of Health and Ageing "Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting", 2004.

Endoscopes are widely used in gastroenterology, respiratory medicine and in a number of surgical specialties. These instruments are expensive and easily damaged. Flexible and rigid fibre optic endoscopes and endoscopic accessory equipment present particular problems in terms of cleaning, disinfection and sterilisation.

The problems of effective reprocessing to avoid CJD transmission are more complicated with the recognition that there may be prion concentrations in lymphoid tissue in variant CJD – the implications of which are still unclear. (Refer “Infection Control in the Health Care Setting” 2004: Sections 17 & 31)

PROCESSING ENVIRONMENT

There shall be a well-ventilated, adequately sized processing environment, with designated ‘clean’ and ‘dirty’ areas. The processing facility and associated equipment and chemicals shall comply with the requirements of WorkSafe Australia, occupational health and safety legislation and guidelines and the Therapeutic Goods Administration. (AS 4187-2003)

PROCESSING OF ENDOSCOPES

Quality management systems should be in place to ensure that there is detailed documentation of all procedures relating to all aspects of reprocessing endoscopes and accessory equipment. Accurate records must be maintained of all steps undertaken in reprocessing. This is essential for any retrospective investigations relating to possible infections.

Flexible and rigid endoscopes and their accessory items are extremely fragile and expensive and, because of their complex construction are very difficult to clean. It is essential that every person responsible for endoscope decontamination familiarise themselves with the particular characteristics of each model of endoscope they are required to clean. Staff involved in endoscope processing and handling shall receive education, training and assessment to ensure they understand how the equipment works, correct cleaning, processing and sterilisation/disinfection and monitoring procedures, along with education regarding the safe use of chemical disinfectants and sterilants. (AS 4187-2003)

Inadequate cleaning has resulted in the transmission of infection including Hepatitis B, C and HIV. The time required for any method of disinfection or sterilisation to be effective depends upon the number of organisms to be destroyed. It is important to reduce the number of organisms to a minimum before exposing the equipment to the sterilising or disinfecting process. Thus fastidious physical cleaning is the single most important factor in achieving high levels of disinfection or sterilisation of endoscopes.

Some materials used in the construction of endoscopes are unable to withstand steam or dry heat sterilisation and may only be sterilised using low temperature sterilisation. Ethylene oxide sterilisation requires prolonged contact times and incurs a three day turn around time; therefore, the preferred means of sterilisation are usually not practical for flexible endoscopes. Flexible endoscopes may also be intolerant to prolonged soaking in some disinfectants. Immersion in glutaraldehyde/OPA is a suitable process for items not intended to enter a sterile cavity.

All accessory equipment, used to breach the mucosa or enter sterile areas such as biopsy forceps and snares, should be cleaned using an ultrasonic cleaner. Sterilisation (steam or ethylene oxide, or peracetic acid) should follow the cleaning process. Items that are designated single use items should not be reused.

Automated utensil washer/disinfector machines are not an appropriate alternative to manual cleaning and should not be used to decontaminate endoscopes prior to sterilisation/high level disinfection.

ENDOSCOPE CLEANING

FLEXIBLE ENDOSCOPES

Immediately on removal of the instrument from the patient, the endoscope shall be wiped from control head to distal tip using clean cloth soaked in clean water an enzymatic cleaning solution (diluted as per manufacturers' instructions). The internal suction channel shall be aspirated with enzymatic solution, depressing and releasing suction button to promote debris dislodgement. Depress and release air/water buttons to flush water through water channel and air through air channel (where applicable use air/water cleaning adaptors as per manufacturers' instructions). It is important to commence processing of the endoscope immediately following procedure to prevent adherence of bodily fluids. It is impossible to adequately disinfect or sterilise an endoscope when organic material has been allowed to dry on the endoscope.

Prior to disassembly and further cleaning of the endoscope **the leak test** shall be performed as per manufacturer's instructions. In the case of video endoscopes the protective cap should be applied prior to leak test.

The flexible endoscope and all reusable accessory items shall be disassembled as far as practicable. The components should be cleaned with an enzymatic solution (diluted as per manufacturers' instructions). Any taps shall be opened and the channels/lumens of the endoscope shall be brushed to remove any adherent debris, if the cleaning brush has obvious debris, it shall be washed prior to being withdrawn through the channel. Sites such as nozzles, flaps, hinges, crevices and joints of accessory items should be cleaned with a soft brush to remove any adherent debris. This cleaning process should continue until the endoscope, its channels, buttons and valves and accessory equipment are completely clean. Accessory items, including buttons shall be placed in an ultrasonic washer according to manufacturers' instructions, it is mandatory for spiral coiled accessory equipment to be thoroughly cleaned in the ultrasonic washer.

Meticulous flush rinsing should be carried out to remove any traces of enzyme/detergent from all channels including auxiliary and bridge channels and accessory items following immersion in ultrasonic washer. All channels are then purged with medical grade air (≤ 160 kPa) to expel as much water as possible, and the external surface is dried with a lint free cloth prior to disinfection. If items are wet when placed into the disinfectant, dilution of the glutaraldehyde/OPA solution will occur (and so decrease the efficacy of the disinfection process).

It is important that all organic material and enzymatic solution must be removed from the instrument prior to soaking in glutaraldehyde/OPA, as these chemicals will "fix" these substances onto the working channels of the endoscope.

Brushes used in the cleaning process for each endoscope shall be cleaned and thermally disinfected after each use.

Note: Fibre optic endoscopes should only be subjected to ultrasonic cleaning in accordance with manufacturers' instructions. Some accessory instruments have extremely small lumens or are too fine or difficult to dismantle for cleaning. In these situations it is impossible to ensure thorough cleaning and decontamination has occurred, in which case consideration should be given to using a single-use accessory.

RIGID ENDOSCOPES

Immediately following use, the rigid endoscope and accessory items shall be wiped clean of visible debris. If the endoscope and associated items cannot be immersed, they shall be wiped with a moistened detergent impregnated lint free cloth and rinsed with a moistened lint free cloth.

The rigid endoscope and all reusable accessory items shall be disassembled as far as practicable. The components should be cleaned with a detergent solution (diluted as per manufacturers' instructions). Any taps shall be opened and the channels/lumens of the endoscope and the joints of accessory instruments shall be brushed to remove any adherent debris, if the cleaning brush has obvious debris, it shall be washed prior to being withdrawn through the channel. This cleaning process should continue until the endoscope and accessory instruments are completely clean.

Meticulous flush rinsing should be carried out to remove any traces of detergent from all channels and surfaces of the endoscope.

Rigid endoscopes and accessories, which do not have any fibre-optic light carriers or cables, may be dried in a drying cabinet. Accessory items may also be dried using low-pressure medical grade air (≤ 165 kPa).

On completion of the cleaning, rinsing and drying process, the rigid endoscope and associated instruments shall be reassembled, inspected and checked to ensure they are not damaged and are in working order, and then disassembled prior to sterilisation.

Brushes used in the cleaning process for each endoscope shall be cleaned and thermally disinfected after each use.

ENDOSCOPE DISINFECTION

Glutaraldehyde/OPA has a wide range of antimicrobial activity and is effective against viruses including HIV, Hepatitis B and C and the majority of bacteria, although spores and mycobacteria species are relatively more resistant.

Factors affecting the efficiency of a disinfectant -Water carried over from the washing and rinsing process reduces the concentration of glutaraldehyde. Organic matter may inactivate glutaraldehyde. Repeated use of the disinfectant may also cause a reduction in the concentration of the solution. It is essential that the instruments soaked in the solution must be cleaned thoroughly and dried prior to immersion. A strict protocol of cleaning and drying of equipment together with frequency of usage of the glutaraldehyde should be in place. Manufacturer's recommendations on the management of glutaraldehyde should be followed.

The solution is at a 2% concentration initially. It is undesirable for this to fall below 1.5%. When the glutaraldehyde solution will require changing will depend on usage. Where endoscopy is being performed infrequently, the glutaraldehyde solution should be disposed of at the end of the day. Chemical indicators should be used to ascertain the concentration of glutaraldehyde. These processes must be documented and monitored.

Endoscopes and accessories, which are soaked in a chemical disinfectant solution prior to use, cannot be considered sterile.

The methods for the soaking and rinsing of the endoscope must be conducted in an aseptic manner

FLEXIBLE ENDOSCOPES

The flexible endoscope shall be leak tested, clean and dry prior to placement in the liquid disinfectant solution.

Manual disinfection-Totally immerse the endoscope, valves and buttons in the disinfectant solution (diluted as per manufacturers instructions). Use a syringe to flush the disinfectant solution down all lumens and channels, to remove airlocks and to ensure all internal surfaces are in contact with the disinfectant. The endoscope should be soaked as per recommended guidelines dependent on the type of endoscope, strength and temperature of the solution. Disinfectant solution should be monitored for concentration levels daily or immediately prior to use.

Flexible endoscopes other than bronchoscopes should be totally immersed in 2% glutaraldehyde/OPA for a minimum of 10 MINUTES between cases and prior to and end of each list.

Bronchoscopes should be totally immersed in 2% glutaraldehyde for a minimum of 20 MINUTES between cases and prior to and at the end of each list.

OPA is not to be used for processing of urological instruments due to a rare risk of anaphylaxis noted in previous patients with a history of bladder cancer.

Automated flexible endoscope reprocessing units-The endoscope is placed into and connected to the machine and appropriate disinfection cycle chosen in accordance with manufacturer's instructions dependent on the type of endoscope. The reprocessing machine should be routinely monitored as per recommended guidelines and manufacturers instructions.

RIGID ENDOSCOPES

Disinfection is not a sterilising process and shall not be used to prepare items intended for entry into sterile body cavities, or which penetrate the mucosal barrier. Rigid endoscopes are critical items and shall only be sterilised prior to reuse

POST DISINFECTION RINSING

After soaking, each channel of the endoscope shall be thoroughly flush rinsed with good quality water. It is increasingly recognised that hospital tap water may be contaminated with a variety of microorganisms. The principal risks of contaminated water in endoscopy units are that endoscopes will become contaminated during the washing or rinsing process and those organisms will proliferate in damp areas of the endoscope during storage.

It is recommended that the quality of water delivered to the unit be examined on a regular basis. If significant contamination or high mineral content exists, filters are required to be installed at the collection point. Water for the final rinse of all gastrointestinal endoscopes should be of high quality, filtered and free from microorganisms able to cause clinical disease eg. Pseudomonas. Bacteria free water filtered through 0.2um filters or sterile water must always be used for final and between patient rinsing of the duodenoscopes, endoscopes used in ERCP and bronchoscopes.

NB. To avoid contamination of the water feed channel in ERCP procedures sterile bottled water or 0.2 um filtered water must be used and the water bottle and tubing sterile and changed between each patient.

Water guns should NOT be used for rinsing, as there is no reliable method of ensuring that the gun and tubing are not contaminated.

Endoscopes processed in an automated reprocessing unit may not require rinsing on completion of cycle, check manufacturers instructions and description of cycle used.

STERILISATION

FLEXIBLE ENDOSCOPES

Most flexible endoscopes (check manufacturers instructions) can withstand a process capable of sterilisation using low temperature ($\leq 55^{\circ}\text{C}$). These processes include ethylene oxide, hydrogen peroxide and peracetic acid. Accessory items capable of withstanding steam sterilisation should be processed by this method.

RIGID ENDOSCOPES

A rigid scope with external detachable optics can and should be sterilised by steam. Any scope that the manufacturer declares to be suitable for sterilisation, should undergo steam or other appropriate sterilisation method (eg. ethylene oxide, peracetic acid, or low temperature plasma). Where sterilisation is by a wrapped process, the packaging material or system used shall be in accordance with the method of sterilisation used (as per manufacturers' instructions). Consideration as to the ability of the endoscope to withstand steam/low temperature sterilisation should be given prior to purchase of rigid scopes. **If items used for surgery will not tolerate sterilisation, consideration should be given to; the purchase of rigid scopes that can undergo a sterilisation process, or single use items.**

DRYING AND STORAGE OF ENDOSCOPES

FLEXIBLE ENDOSCOPES

The endoscopes must be thoroughly dry before being stored. Sterile isopropyl alcohol 70% shall be used to assist forced air-drying of channels. This reduces bacterial growth during storage. Denatured alcohol eg. Methylated spirit should not be used for drying as it can damage components of flexible endoscopes. Some manufacturers do not recommend the use of alcohol, in which case it should not be used.

Endoscopes processed in an automated reprocessing unit may not require drying on completion of cycle, check manufacturers instructions and description of cycle used.

Endoscope storage is preferably, by hanging at full length with insertion tube as straight as possible, on appropriate support structures, rather than coiled in a case. The storage area should be a dedicated cupboard for that purpose, be well ventilated and be clearly indicated as such.

The storage area and its vicinity should have limited traffic flow, and be free from dust, insects or vermin.

After storage all endoscopes must be disinfected/sterilised prior to use.

RIGID ENDOSCOPES

Rigid endoscopes that have undergone sterilisation as a wrapped item shall be stored in accordance with Section 9, Clause 9.2.1- AS 4187-2003. Endoscopes that have undergone chemical sterilisation as an unwrapped item shall be stored dry in accordance with Section 9, Clause 9.1.2 – AS 4187-2003

STAFF PROTECTION

All those working in the operating room or endoscopy unit or SSU unit should have received Hepatitis B immunisation and be aware of their TB immunity.

When manually cleaning endoscopes and associated equipment standard precautions are essential staff should wear appropriate protective equipment (gloves, impervious gowns, plastic aprons, splash-resistant masks, safety eyewear and face protection).

Mucocutaneous transmission of blood borne viruses has occurred from splashing of blood and secretions. Therefore all staff including surgeons, endoscopists and their assistants should wear gloves, protective or waterproof gowns, and close-fitting eye wear with all patients undergoing procedures that create exposure to blood or bodily substances and when undertaking cleaning/disinfection procedures.

It is not possible to identify infectious patients therefore standard precautions should be practised. Patients undergoing bronchoscopy should be treated as potentially infectious for respiratory borne illness, and additional precautions used. A mask (P2 particulate filter) together with other protective equipment should be worn.

Note: Glutaraldehyde has been identified as a hazardous substance. It is toxic, irritant and allergenic and can give rise to contact dermatitis or occupational asthma. It is therefore essential that safe working practices be adopted to minimise the risk of vapour inhalation, skin and eye contact. Personal protective equipment should be available for all staff.

Glutaraldehyde should be stored in closed containers with well-fitting lids. The disinfection procedure may be performed in a closed system or in a well ventilated area, preferably under a fume-hood to keep the level of glutaraldehyde in the air below 0.1 parts per million.

STAFF EDUCATION

Staff performing the cleaning and disinfection should have completed a competency based education program to ensure they understand how the equipment works, the correct handling processing and sterilisation/disinfection procedures and the hazards with the use of chemical disinfectants.

ROUTINE MICROBIOLOGICAL TESTING

The modern endoscope is honeycombed with multiple small channels, some with blind endings, which cannot be adequately inspected visually. Microbiological testing of the scopes is used to verify effectively that the cleaning and disinfection process is adequate. Routine cultures will provide early warning signs of any detected fault in the internal structure as well as providing a quality control check on the cleaning and disinfection process.

Microbiological sampling should be undertaken in accordance with GENCA Guidelines “Microbiological Testing of Gastrointestinal and Respiratory Endoscopes and Automated Flexible Endoscope Reprocessors” updated February 2008. Interpretation of the results should be in discussion with microbiologist and Infection Control Co-ordinator.

Every healthcare facility has a responsibility to ensure that the water supply delivered to the facility is of high quality. Various methods may be implemented to improve the quality of the water throughout as well as to endoscopy units.

Water quality delivered to AFER’s and used for final rinse of scopes must be monitored by bacterial culture on a regular basis. The frequency of monitoring will depend on the quality of the water delivered to the unit.

Biological Monitoring: Recommended Frequency of Testing

Due to different risks of infection transmission testing frequency varies with the use of endoscopes and methods of processing.

Recommended Biological Monitoring of Endoscope Reprocessors (AFER's)

Reprocessor Type	Frequency
Steris	Weekly
Soluscope	4 weeks
Medivator	4 weeks
GUS	Organisation discretion
Fume Cabinet	Organisation discretion

*Disinfection reprocessors as per GENCA guidelines February 2008, other units as per manufacturers' instructions or organisation discretion as units are not automated

Endoscope Type	Frequency
Bronchoscopes	4 weeks
Duodenoscopes	4 weeks
Gastrosopes	3 months
Colonoscopies	3 months
Other flexible gastrointestinal	3 months

Endoscopes processed through a **sterilization process** and stored wrapped to be biologically tested every **3 months**.

Loan Endoscopes to be tested within 2 days of receipt and then as per above schedule for the duration of the time on loan

*Recommendations derived from **GENCA** "Microbiological Testing of Gastrointestinal and Respiratory Endoscopes and Automated Flexible Endoscope Reprocessors" updated February 2008. **GENCA** recommendations should be followed as in Australia this body is recognised as having the leading experts in this field.

Further Testing Recommendations:

1. If major changes are made to the cleaning regimen, unit personnel, if there is clinical suspicion of cross infection related to endoscopy, alterations to plumbing to the unit, new models of equipment or in response to positive surveillance culture then microbiological screening should be undertaken in conjunction with consultation with a clinical microbiologist.
2. Routine microbiological sampling for Mycobacteria Tuberculosis is not recommended for rigid and flexible fibre optic bronchoscopes but should be undertaken at the next scheduled sampling if bronchoscope had been used on a patient who had a positive M. tuberculosis culture.

Action for Positive Results:

If a growth is detected the scope must be decommissioned until it is thoroughly cleaned and disinfected. The scope remains decommissioned until pathology results are returned and all clear. Careful inspection of the scope for defects is essential.

If a growth is positive from an AFER it must be removed from service until thorough checking and cleaning has been undertaken and culture results are negative.

All variances should be reported to the Infection Control committee as a key performance indicator for risk management.

Refer to Appendix 1 GENCA "Microbiological Testing of Gastrointestinal and Respiratory Endoscopes and Automated Flexible Endoscope Reprocessors" February 2008

TRACKING OF ENDOSCOPES

Endoscopes must be tracked to the patient and records kept in the department and patient history. The records shall include, but not limited the following information:

1. Date of Procedure
2. Name of patient and date of birth
3. Instrument and serial number/code linked
4. Order of patients examined on the list
5. Name of the person/s who manually cleaned, rinsed, disinfected and final rinsed the instrument/s. Computer printouts from automated endoscope reprocessing machines may be attached to the patient's health record.
6. Daily records of the concentration of chemical disinfectant
7. Name of person who connected the instrument to the automated flexible endoscope reprocessor or chemical sterilisation unit
8. Accessory items which are used for each patient that have been sterilised, have chemical indicator label inserted into log book beside patient name demonstrating proof of subjection to process (cycle met sterilisation parameters). If item not wrapped but processed through steriliser, the serial and load number details are recorded into log book beside patient name.
9. Records are kept of all microbiological sampling undertaken and results on all endoscopes and endoscope processing equipment for reference.

LOAN ENDOSCOPES

Loan endoscopes will be processed in accordance with sections 9.2.1-6. The loan endoscope must undergo these processes prior to first use and after last use within the facility using the loan endoscope. Microbiological monitoring history of the endoscope should be available to facility using loan endoscope. A memorandum of understanding between endoscope owner and facility loaning the scope will be implemented to ensure appropriate monitoring has been undertaken.

REPAIR OF ENDOSCOPES

Endoscopes required to be sent for repairs, shall be processed in accordance with 9.2.1-6. If the endoscope is unable to be processed due to damage, then the endoscope shall be returned to the manufacturer/owner unprocessed in a sealed container and labelled to indicate that the endoscope is unprocessed, with relevant hazard warning and meet requirement for transport of such goods.

REFERENCES:

Mayhall C.G., Hospital Epidemiology and Infection Control: Williams and Wilkins, 1996, Chapter 47.

Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting. Australian Government Department of Health and Ageing, 2004.

Block S.S., Disinfection, Sterilisation and Preservation, Fourth Edition, Lea & Febiger, 1991, Ch 34 & 35.

Rutala W.A. "APIC Guidelines for selection and use of disinfectants": American Journal of Infection Control (1990) 18: 99-117.

Cowen A., Jones, D., Wardle E., "Infection Control in Endoscopy Guidelines". Gastroenterological Society of Australia & Gastroenterological Nurses College of Australia: 2nd Edition 2003

Cowan A.; Davis L.; Everts R.; et al, "Microbiological Testing of Gastrointestinal and Respiratory Endoscopes and Automated Flexible Endoscope Reprocessors" February 2008 available at:

http://www.genca.org/html/s01_home/home.asp?dsb=10

Standards Australia Code of Practice for Cleaning, Disinfecting and Sterilising for Reusable Medical and Surgical Instruments and Equipment: AS 4187 -2003.

Johnson & Johnson k.k., Cidex OPA Solution, Material safety data sheet, 2006

(Insert Name of Organisation) Endoscopy Service

MEMORANDUM OF UNDERSTANDING

This memorandum of understanding outlines the responsibilities of the nominated parties for the cleaning, processing and biological monitoring of the rotating loan endoscopes used within this organization.

RESPONSIBILITIES

ENDOSCOPE OWNER

The endoscope owner will ensure that the endoscope is cleaned, processed, dried, handled, stored and biologically monitored in accordance with recommended standards and guidelines. The owner will ensure that automated units, if used to process the endoscope, are biologically, chemically and physically monitored in accordance with manufacturers' instructions and with recommended standards and guidelines.

Payment for microbiological analysis of the samples taken from the endoscope/s is the responsibility of the owner of the endoscope/s unless otherwise negotiated with the organization/s in which the endoscope is used.

ENDOSCOPY SERVICE PROVIDER

The party responsible for the transport of the endoscope between organizations will ensure that the endoscope is packaged and transported to minimize contamination prior to arrival to this organization.

ENDOSCOPE USER

The organisation using the endoscopes ensures that the endoscope is cleaned, processed, dried and handled in accordance with recommended standards and guidelines. The automated units, if used to process the endoscopes, are biologically, chemically and physically monitored in accordance with manufacturers' instructions and with recommended standards and guidelines.

BIOLOGICAL MONITORING

The nominated party as identified in the 'agreement' will ensure that biological monitoring of the endoscope described below is in accordance with recommended standards and guidelines.

The nominated party 'agrees' to undertake biological monitoring of the endoscope specified below, which includes;

Taking the biological sample and sending the sample for microbiological analysis

Recording of test results on endoscope monitoring history sheet,

Reporting test results to relevant organisations to whom the scope is also on loan, and to the owner of the endoscope.

Endoscope Brand and Type

.....

Endoscope ID Number

.....

Endoscope Owner

.....

Endoscope Users (other organisations)

.....

MEMORANDUM OF UNDERSTANDING

Agreement

I,
(Owner of endoscope e.g. surgeon, or representative of organization if endoscope owned by that organization e.g. NUM theatre)

On behalf of,

.....

(myself, organization)

agrees to

.....

(myself, organization)

being the nominated party responsible for undertaking the biological monitoring of the endoscope as outlined on page 2.

The nominated party delegates responsibility to the following persons

..... will be responsible for taking biological sample and sending it to be analysed

..... will be responsible for recording of test results

..... will be responsible for reporting of test results

..... will be responsible for payment of the biological monitoring

Signed.....

Name and Title (please print).....

On behalf of the Organisation using the Endoscope - (please print)

.....

Date..... /...../.....

Signed.....

Name and Title (please print).....

On behalf of the Endoscope Owner- (please print)

.....

Date..... /...../.....

Positive Test Result **Action Plan**

The person nominated to receive the test results (Refer Endoscopy Service- Memorandum of Understanding) should contact the Director of Medical Services and or the Infection Control Practitioner, and person in charge of Endoscopy Unit where the endoscope has been used to formulate a working party and action plan.

There is currently no mandatory requirement to contact the Department of Human Services in the event of a positive microbiological test result from either an endoscope or automated endoscope reprocessor.

Positive test results should be identified as a 'potential critical incident' and although it is not mandatory to report results as described above, the Department of Human Services suggests that the Regional Office in your area be contacted in the event the issue progresses to a critical incident, with the possibility of media exposure and community knowledge occurring. As such the organisation should implement the critical incident management plan and identify the contact /liaison person for the organisation.

Interpretation of the results to determine Clinical Significance

In the event of a positive test result identify the organism and level of growth. Consult microbiologist to determine possible origin of the isolate (water borne, environmental, skin flora etc) to eliminate contamination at time of sampling as source of positive result. Discuss the significance of the result with microbiologist and potential outcomes for patients exposed to; the endoscope with a positive test result, or endoscopes processed in an automated machine with positive test result. Re-test to determine if isolate is still insitu.

Actions

Contact other organisations (if any) that have used the same endoscope following the positive test result.

Contact the owner of the endoscope (if not another organisation). Discuss clinical significance and actions your organisation is taking in response to positive test result.

Dependent on the clinical significance of the results the organisation must decide upon actions that reflect the risk management strategy and critical incident action plan. This may or may not include contact tracing of patients exposed to or potentially exposed to an endoscope with a positive result, or endoscopes processed through automated reprocessor with positive result.

The identified endoscope/automated endoscope reprocessor history must be checked to determine if a positive result has occurred before, if so, when, and what isolate was identified. Review all cleaning, processing, physical condition and maintenance records of endoscopes/automated endoscope reprocessor. Check water supply and filtering systems to automated processors, also check that chemical agents used in the processing are not contaminated, diluted or being used at the wrong strength.

If required, withdraw the endoscope/endoscope processor from use until tests prove the unit to be biologically safe for use as determined by your working party. Review the need to import temporary equipment, or postpone endoscopy lists until issue is resolved.

Write up report of the incident, actions taken and any outcomes. Keep Regional Office of DHS, other organisations and parties involved in this issue informed of progress and outcomes.

**ENDOSCOPE RECORD
MICROBIOLOGICAL TESTING HISTORY
To be kept with endoscope**

EXAMPLE ONLY

ENDOSCOPE ID NUMBER AND TYPE *657854321-Gastroscope-pentax*

ENDOSCOPE OWNER *Dr G Bell*

ROUTINE MICROBIOLOGICAL MONITORING MONTHLY-if endoscope is processed at any site in an Automated Endoscope Reprocessor
4 MONTHLY-if processed by sterilisation or manual disinfection process

Name of party responsible for testing of endoscope (as identified on MoU)	Date this sample taken	Sample taken by	Testing Agent Used	Pathology Department processing sample	Endoscope biological test result and date sample taken	Signed	Additional comments
<i>St Margarets</i>	<i>25/10/01</i>	<i>Jim Beam</i>	<i>Ringers solution</i>	<i>Northwest Pathology</i>	<i>Pass 25/10/01</i>	<i>xxxxxxx</i>	
<i>St Margarets</i>	<i>23/2/02</i>	<i>Jim Beam</i>	<i>Ringers solution</i>	<i>Northwest Pathology</i>	<i>Pass 23/2/02</i>	<i>zzzzzzzz z</i>	

**ENDOSCOPE RECORD
PROCESSING HISTORY**
To be kept with endoscope

EXAMPLE ONLY

ENDOSCOPE ID NUMBER
AND TYPE

657854321-Gastroscope-pentax

ENDOSCOPE OWNER

Dr G Bell

INFORMATION TO BE ENTERED AT EACH SITE THAT ENDOSCOPE IS USED

Name of Hospital or Endoscopy Unit	Date Endoscope used	Type of Processing Unit and ID Number	Chemical Agent Used	Processing Unit's last known biological test result and date test taken	Signed	Additional comments
<i>St. Elsewhere's</i>	<i>20/7/02</i>	<i>Soluscope 2345</i>	<i>Glutaraldehyde</i>	<i>Pass 26/6/02</i>	<i>xxxxxxx</i>	<i>Processed 5 times</i>
<i>Prince Charles</i>	<i>23/7/02</i>	<i>Steris 6789</i>	<i>Peracetic acid</i>	<i>Pass 7/7/02</i>	<i>zzzzzzzz</i>	<i>Processed 6 times</i>

9.3 Ultrasound Probes

RATIONALE

The type of procedure being undertaken will influence the level of equipment reprocessing required to prevent patient-to-patient transmission of infection. This reprocessing level is dependent upon the site and the type of procedure being performed.

The classification of patient equipment into one of three different categories can be utilised to assess the level of reprocessing required for ultrasound probes. In general they will fit into the **semi critical** (transvaginal, transrectal and transoesophageal) or **non-critical** categories. Ultrasound probes are also used for sterile (**critical**) situations including renal and hepatic studies, for review of vascular surgical repairs and for some endobronchial and gynaecological operations.

PRECAUTIONS

Standard precautions should always apply where there is a potential for contact with blood, body fluids or mucous membranes.

CRITICAL

Equipment that enters sterile tissue, sterile cavities or vascular system. *Example:* Intra-abdominal ultrasound probes, renal, hepatic, and hepatobiliary studies, for the review of vascular surgical repairs and for some endobronchial and gynaecological operations.

Diagnostic ultrasound transducers that are to be used in sterile (critical) sites must be sterile and only transducers that are capable of being sterilised should be used. Low temperature chemical sterilising technologies suitable for processing heat sensitive items include the peracetic acid and hydrogen peroxide plasma sterilisation systems.

SEMI CRITICAL

Equipment that will have close contact with mucous membranes and broken skin (eg. dermatitis, psoriasis). *Example;* Transvaginal, transrectal and transoesophageal ultrasound probes.

These items require sterilisation (if possible) or at least, high level chemical disinfection. When transducer probes have direct contact with mucous membranes (e.g. vaginal probes) they should be covered for the procedure with a disposable impermeable cover. After every patient use the probes must be reprocessed by thorough cleaning in warm water and detergent and soaked in a TGA registered high-level instrument grade disinfectant or sterilant. Unless sodium hypochlorite is labelled as a high-level instrument-grade disinfectant it is not suitable for reprocessing these instruments. After disinfection the instrument should be thoroughly rinsed and dried before re-use with a new sheath. (Although use of a disposable cover reduces the level of risk of transmission or contamination, covers can be perforated or contain small unrecognised defects).

For abdominal ultrasound where there is an open wound, a disposable cover should also be used. After the procedure, dispose of cover and reprocess the probe.

NON CRITICAL

Items that only have contact with intact skin. *Example:* Ultrasound probes used on intact skin

These items require thorough physical cleaning with water and neutral detergent in accordance with manufacturer's instructions. Probes must be stored clean and dry.

USE of SLEEVES/SHEATHS

The use of sleeves / sheaths as an instrument cover during procedures is not a substitute for cleaning and disinfection/sterilization processes between every patient use.

Where a disposable physical covering is used to enclose the probe care should be taken to ensure the cover does not detach during the procedure.

The disposable cover should be thick enough to resist tearing or perforation during use. The preferred option is water-repellent polyethylene surgical drape sheeting (at least 38um thick). Its thickness makes it a more reliable barrier. The use of commercially available plastic wrap as a protective barrier is not recommended. Specifically designed disposable sheaths may be available. Less effective alternative covers include condoms and gloves. A material other than latex should be used for patients who are known to be latex-sensitive.

At the end of each procedure, the cover should be removed and discarded, taking care not to contaminate the surface of the instrument. After removal the instrument should be cleaned with warm water and a neutral detergent in accordance with the manufacturer's instructions. After cleaning the instrument **must** be processed according to the purpose for which it will be used – critical, semi-critical or non-critical

GEL

Ensure that there is no risk of contamination of the gel used during the procedure. For surgical use, the gel must be sterile. Gel containers should not be refilled or reused, because they may have become contaminated and could be a potential source of infection.

REFERENCES:

Australia/New Zealand Standard: AS/NZS 4187 – 2003.

Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Healthcare Setting. Australian Department of Health and Ageing, 2004.

Australia Government Department of Health and Ageing: Therapeutic Goods Administration [TGA] "Therapeutic Goods Order No. 54 STANDARD FOR DISINFECTANTS AND STERILANTS" February 1998 available at: <http://www.tga.gov.au/docs/html/tgo/tgo54.htm>

Storment JM. et.al., Ineffectiveness of latex condoms in preventing contamination of the transvaginal ultrasound transducer head: Southern Medical Journal. Feb. 1997.

State Government of Victoria, Australia, Department of Human Services –Victorian Government Health Information: "Hospital Circular 01/ 2008 – Reprocessing Intracavitary Transducers" available at: <http://www.health.vic.gov.au/hospitalcirculars/circ08/>

INFECTION PREVENTION AND CONTROL MANUAL

9.4 Re-use of Single Use Medical Equipment

DEFINITIONS

Re-process: the packaging and sterilisation of a device that has been opened but not used

Re-sterilisation: the sterilisation of an unopened sterile device

Re-use: the cleaning, packaging and sterilisation of a single-use medical device after use on a patient for the intended purpose of using it on another patient.

RATIONALE

The Health Service does not approve the re-use, reprocessing or re-sterilization of any medical item, which is labelled by the manufacturer as single use or single patient use.

Instruments labelled 'single-use device' should be discarded after use, in accordance with manufacturers' recommendations and consistent with their TGA approval status.

The Australian/New Zealand Standard AS4187-2003 condemns the practice of reuse of single-use items and states that they should be discarded at the point of use.

The National Coordinating Committee on Therapeutic Goods (NCCTG) extended transition timeframe to 1 July 2007 for Hospitals to cease re-manufacturing semi critical and non critical single use items.

Since 1 July 2007, any reprocessing of single use medical devices is seen as a manufacturing activity regulated to the same level as the original manufacturer.

Health services wishing to reprocess, must therefore apply and meet TGA requirements of a manufacturer before undertaking reprocessing.

The legislation applying to remanufacture of single use medical devices is:

The Therapeutic Goods Act 1989

The Therapeutic (Medical Devices) Regulation 2002

The Therapeutic Goods Regulations 1990

REFERENCES:

Australian/New Zealand Standard. AS/NZS 4187-2003. Code of practice for cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environmental in health care facilities.

The Therapeutic Goods Act 1989, No 21 of 1990, S. 14. (1). Report of the NHMRC Expert Panel on Re-use of Medical Devices Labelled as Single Use. 1996.

Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Healthcare Setting. Australian Department of Health and Ageing, 2004.

Therapeutic Goods Administration, Fact sheet no.37, Oct 2006

www.tga.gov.au/devices/fs-sudman.htm (accessed 11/2007)

9.5 Storage and Handling of sterile stock

RATIONALE

Sterile items will be stored and handled in a manner that maintains the integrity of packs and prevents contamination from any source. Sterile storage areas will be clearly indicated and controlled to prevent contamination of sterile stock. Storage areas must be dedicated for that purpose only. This policy applies to the storage and handling of sterile stock from the supply department to the end user.

For ward areas, the dedicated area may be shelves or cupboards, and these need to be clearly marked to ensure all staff are aware of the nature of the product being stored.

STORAGE:

The storage area must be kept clean and free of dust, insects and vermin.

Storage containers will be clean, dry and in good condition.

All items will be stored at least 250 mm from the floor level, and at least 440 mm from the ceiling and protected from direct sunlight.

Cardboard boxes should not be used as they are porous, cannot be cleaned and they may harbour organisms.

Commercial dispenser boxes must not be topped up or reused.

Temperatures within the storage area should range from 18°C Celsius to 22°C Celsius, with a relative humidity of 35% to 68%.

Air conditioning and ventilation conditions will be in accordance with Australian Standard 1668.2.

**STORAGE AND HANDLING OF STERILE ITEMS APPLY EQUALLY TO COMMERCIALY PRE-PACKED ITEMS AND ITEMS STERILISED WITHIN THE HEALTH CARE FACILITY.
(Refer to AS/NZS 4187 – 2003, Clause 9.2.1)**

TRANSPORTATION / DISTRIBUTION OF STERILE ITEMS

All items transported will be delivered in a clean container, trolley or vehicle dedicated to that purpose.

To guarantee sterility of items transported several procedures must be adhered to.

Containers, vehicles, trolleys and hoists used for the transportation of sterile goods must not be used for the collection of used items, transportation of food or garbage.

All transportation equipment is maintained in a clean, dry condition and in good working order.

All sterile items for distribution outside the Health Care facility must be securely packed and protected against damage and contamination during transportation.

There must be a regular cleaning program for all sterile storage areas, including all containers and trolleys.

(Refer to AS/NZS 4187 – 2003, Clause 9.4)

COMMERCIALY PREPARED ITEMS

Grossly soiled or damaged stock should not be accepted as contents may be compromised.

Dust must be wiped from store pack before opening to prevent contamination of inner items.

Remove sterile items from the store pack before bringing them into the clean area.

Inspect unit packs or their contents for cleanliness or damage before use.

(Refer to AS/NZS 4187 – 2003, Clause 9.5)

ROTATION OF STOCK / SHELF LIFE

Good management practices demand stock be maintained at adequate levels and rotated on a “first sterilised – first used” basis.

The system of stock rotation is based on date of sterilisation.

Handling of sterile stock is kept to a minimum as, each time the stock is handled, there is an opportunity for inadvertent contamination through damage to packaging. Do not stack stock too tightly into storage containers or wrap with elastic bands as packaging may be damaged.

PROCEDURE

1. All packaging materials must be adequate to cover the item and meet AS/NZS 4187-2003.
2. They must meet all storage and handling conditions
3. All packaging must be checked for deterioration, and carefully monitored.
4. Package design must meet Australian Standards.

NOTE:

Adequate levels must be maintained and monitored to guarantee quality management. This applies to manufactured pack / items and commercially pre-packed items.

(Refer to AS/NZS 4187 – 2003, Clause 9.6.1)

CONTAMINATED SUPPLIES

Contaminated supplies are totally unsuitable for use when considered so, and will be closely monitored as part of a quality management program.

Any contaminated items shall be discarded in the case of commercially produced items, or decontaminated and re-processed if re-usable items. It shall never be used in a contaminated state.

Items are considered contaminated when:

1. They are wrapped incorrectly or inadequately.
2. When packaging is damaged or opened.
3. Comes in contact with a wet surface.
4. Is placed or dropped on a dirty surface, eg. floor or sink.
5. Has no indication of having been through a sterilising process, eg. chemical indicator has not changed colour, has no batch number
6. Incorrect or inadequate cleaning procedures in the storage area.
7. Stored at incorrect temperature.
8. Excessive exposure to sunlight or ultraviolet light.
9. Evidence of vermin and insects.
10. Sharp objects or rough handling, which may cause damage to packaging materials. i.e. pins, clips or rubber bands must not be used to contain sterile stock.
11. Incorrect handling when transporting items.

(Refer to AS/NZS 4187 – 2003, Clause 9.6.3)

REFERENCE:

Australian/New Zealand Standard AS/NZS 4187- 2003. Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.