Principles of Effective Decontamination Protocols

1. INTRODUCTION

THE MOST IMPORTANT STEP IN THE PROCESS OF ENDOSCOPE DECONTAMINATION IS SCRUPULOUS MANUAL CLEANING PRIOR TO DISINFECTION

DEFINITION

"Manual cleaning" refers to the physical task, performed by hand, of removing secretions and contaminants from the endoscope with appropriate brushes, cloths, detergents and water. It should NOT be confused with "mechanised cleaning" (where a cleaning process is performed by a machine) or "mechanised disinfection" (when a clean endoscope is placed in a machine which disinfects and rinses the instrument).

Mechanised cleaning is not appropriate for endoscopes

In order for manual cleaning to be effective it must:

1. Be performed by a person conversant with the structure of the endoscope and trained in cleaning techniques;

2. Be undertaken immediately after the endoscope is used so that secretions do not dry and harden;

3. Follow a protocol which, using appropriate detergents and cleaning equipment, allows all surfaces of the endoscope, internal and external, to be cleaned;

4. Be followed by thorough rinsing to ensure that all debris and detergents are removed prior to disinfection.
2. EFFECTIVENESS OF RECOMMENDED PROTOCOLS

Hanson et al\textsuperscript{48,49} has shown that recommended protocols removed all microbiological contamination from endoscopes used to examine patients with HIV and HBV infection. They have also confirmed that endoscopes artificially contaminated with serum containing high titres of these viruses have all microbiological activity removed by appropriate reprocessing. These results have been confirmed by a number of other studies. One of the most important is that of Deva et al\textsuperscript{189}. This excellent study made three critical findings:

1. When followed meticulously, recommended reprocessing protocols removed microbiological contamination.

2. That bacterial contamination was an accurate index of viral contamination.

3. That even minor deviations from cleaning protocols resulted in persistent microbiological contamination after disinfection.

Chu et al\textsuperscript{190} has quantitated the dramatic reduction in bio burden levels following effective cleaning of colonoscopes. They have also confirmed the contamination of endoscopes during the cleaning process by water borne organisms including pseudomonas and enterobacteriaceae.

Not all investigators have been able to confirm such satisfactory results in reprocessing. Kovacs et al\textsuperscript{191} reported a strain of \textit{Pseudomonas aeruginosa} responsible for three separate clinical episodes of E.R.C.P. associated cholangitis over an 11 year period. They concluded the organism developed adaptive chemical resistance to glutaraldehyde because it could be recovered from the instrument after stringent recommended reprocessing protocols. Kovacs et al\textsuperscript{192} found that endoscopes artificially contaminated with \textit{Mycobacterium chelonei} did not have all bacteria removed by recommended reprocessing. The clinical implications of this study are less clear since clinical disease is unlikely to occur from \textit{Mycobacterium chelonei}. Cronmiller et al\textsuperscript{193} contaminated colonoscopes with \textit{Enterococcus faecalis} and found some remaining contamination after ten minutes of glutaraldehyde immersion. Bordas et al\textsuperscript{194} found that "in use" tests demonstrated not all bacterial contamination was removed by recommended protocols. Van der Voort et al\textsuperscript{195} and other authors have found remaining HIV RNA on endoscopes when using PCR techniques. However the significance of this was extremely doubtful, particularly since the study of Deva et al\textsuperscript{50} using the duck hepatitis B model has shown that duck hepatitis virus remaining on instruments detected by PCR was not infective when injected into ducks and therefore is likely to represent remaining viral RNA rather than intact infective particles.

The number of organisms detected in most of these studies has been extremely small and of doubtful clinical significance. \textbf{Nonetheless it does emphasise that our present reprocessing techniques are less than ideal and have a lower margin of safety than is desirable.} It emphasises the need for all steps in reprocessing protocol to be carried out meticulously.

3. ENDOSCOPE STRUCTURE

There are at least fifty different models of flexible endoscopes available in Australia. An instruction book is supplied with each endoscope by the manufacturer.

\textbf{IT IS ESSENTIAL THAT EVERY PERSON RESPONSIBLE FOR ENDOSCOPE DECONTAMINATION READS THESE INSTRUCTION BOOKS AND IS FAMILIAR WITH THE PARTICULAR CHARACTERISTICS OF EACH MODEL OF ENDOSCOPE REQUIRED TO BE CLEANED.}
COMMON FEATURES

External

All flexible fibrescopes have a light guide plug, an umbilical cable (cord), a control head and an insertion tube.

(a) The Light Guide Plug

The light guide plug fits into the light source. The air/water and suction channels have ports in the light guide plug.

The light guide plug of a video endoscope is heavier than that of a fibrescope and needs to be handled with care.

(b) The Umbilical Cable/Universal Cord

The umbilical cable connects the light guide plug to the body of the endoscope. The external surface may be contaminated by splashes or hand contact during endoscopic procedures.

(c) The Control Head

The control head contains the control handles, which allow the operator to flex the instrument and to access the suction and air/water functions by use of valves. Fibreoptic endoscopes have an eyepiece on the control head. Video endoscopes are similar in construction to fibreoptic endoscopes, except that they do not have an eyepiece - the image is seen on a video screen. The control head is contaminated during endoscopic procedures by the operator's hands. The control handles have grooved surfaces, which must be carefully brushed during cleaning. The hollow structure of some control handles should be noted and care taken to ensure that the undersurface is thoroughly rinsed and emptied of fluids. The seats, which house the suction and air/water valves (buttons), must be thoroughly cleaned. The biopsy channel port is located at the base of the control handle near its junction with the insertion tube. This port must be brushed carefully during the cleaning process.

(d) The Insertion Tube

The insertion tube enters the patient's body and is grossly contaminated during the procedure. The distal tip of the insertion tube houses the microchip (in video endoscopes), the openings for the suction and air/water channels and the lens covering the flexible fibreoptic light guides. The section of the insertion tube adjacent to the distal tip is known as the bending section. It is made from soft flexible material and is particularly vulnerable to damage especially if handled carelessly.
Common Internal Features

The suction and air/water channels and the fibreoptic light guide extend from the light guide plug to the distal tip. In non-video models an additional fibreoptic bundle, the image guide, extends from the control head to the distal tip. The cables, which allow the tip to be flexed, run through the insertion tube. Any damage to either the umbilical cable or the insertion tube can potentially damage any of the internal structures. Care must be taken during cleaning procedures to ensure that the umbilical cable and insertion tube do not become kinked or acutely bent. **KINKS IN BIOPSY CHANNELS TRAP DEBRIS AND LEAD TO FAILURE OF THE CLEANING PROCESS.** Suspected damage should be referred to the supplier for assessment and repair. A negative leakage test does **NOT** preclude damage to internal endoscope structures.

Special Internal Features

Most duodenoscopes have an additional channel - the forceps elevator (raiser) which is extremely fine (capacity 1-2 mls) and requires scrupulous attention during the cleaning process. Cleaning adaptors for this channel are provided with each duodenoscope AND MUST BE USED.

Some colonoscopes have a carbon dioxide channel (C02) that is connected to the air/water channel. Cleaning protocols should include individual flushing of this channel.

Flush channels are found in some endoscopes. These are usually grossly contaminated during procedures and must be independently flushed during cleaning whether or not they have been used.

4. **CLEANING EQUIPMENT**

All endoscopes are supplied with appropriate cleaning adaptors. It is vital that persons cleaning endoscopes are conversant with these adaptors and use them correctly. Rubber "0" rings on the adaptors must be inspected regularly for defects or looseness and should be replaced as required. Substitute cleaning equipment should not be used unless approved by the supplier of the instrument, e.g. using a syringe to squirt fluid into a port which requires a screw thread adaptor is not safe practice.

Cleaning brushes for both channels and valve ports are also supplied. These have a limited life. They should be inspected regularly and replaced when worn or kinked.

Soft toothbrushes are useful to clean grooved control handles and to brush the distal tip and biopsy ports. Cotton buds may be used to clean the suction valve port but should not be used in the air/water port as threads can become caught and cause blocked channels.

Adequate supplies of disposable cloths or swabs should be available.

5. **CLEANING FLUIDS**

Endoscope suppliers have reported a reduction in channel blockages since the introduction of enzymatic detergents. These products promote protein lysis and enhance the efficacy of brushing and flushing and are the preferred detergent. Where an enzyme product is not immediately available, a neutral instrument detergent can be used. Household detergent is **NOT** suitable. Chlorhexidine based detergents have been reported to damage instruments when followed by glutaraldehyde disinfection and should **NOT** be used.
Manufacturers of enzymatic solutions report optimum efficacy when used in warm water. However, enzymes will continue to be active in water that has cooled to room temperature. The use of hot water will destroy the enzyme activity. Heavy contamination may exceed the enzyme capacity.

6. RINSING WATER

It is increasingly recognised that hospital tap water may be contaminated with a variety of micro-organisms. Pseudomonas and related species, atypical mycobacteria and legionella are the most important frequently detected contaminants. Whether or not the hospital water is contaminated will depend on a wide variety of factors which include the quality of the water delivered to the hospital, the age and particular structure of the hospital plumbing system and hot water temperature. Where the plumbing is old or has been altered, particularly if there are blind endings and where a high flow is not occurring frequently, the risk of contamination is increased. Hot water systems which have the temperature regulated to prevent patient scalding will also increase the likelihood of water contamination. A constant temperature of at least 55°C at the point of use is necessary in order to prevent persistence of organisms in warm water.

The principal risks of such contaminated water in endoscopy units are that endoscopes and accessory equipment will become contaminated during the washing or rinsing process and that the organisms will proliferate in damp areas of the endoscope during storage. It is likely that this is one of the principal mechanisms for colonisation of endoscopes and disinfecting machines.

Organisms contaminating the endoscope or accessory equipment during washing or rinsing steps inbetween patient examinations may be introduced to the next patient on the list. This risk is likely to be extremely small and probably only significant where an invasive procedure, e.g. injection sclerotherapy or E.R.C.P. is undertaken or if the patient has a severely compromised immune system, (e.g. leukaemia, HIV infection). Contamination of biopsy or culture specimens may also cause confusion by falsely suggesting that infection is present, (e.g. pseudo infection). This risk has prompted a call for filtration of all water used to wash and rinse endoscopes. Such a general usage is both difficult, expensive and may carry its own significant problems. Filters which are not changed and/or regenerated (including autoclaving) may in fact become a source of contamination themselves, increasing rather than reducing the problem. In general, however, persisting vegetative pathogens are unlikely to survive in a completely dry environment.

Bacteriological examination of tap water is not simple. The tap mouth should be flamed to eliminate surface gram negatives and at least a litre (preferably more) of tap water needs to be collected. Therefore, a practical alternative to monitoring water quality or filtering water is meticulous air drying of all channels following an alcohol flush after each case.

Recommendations

1. The quality of water delivered to the endoscopy unit be examined on a regular basis. If significant contamination is found then filters should be installed.

2. FILTERED OR STERILE WATER MUST ALWAYS BE USED FOR FINAL AND BETWEEN PATIENT RINSING OF DUODENOSCOPES AND BRONCHOSCOPIES.
3. Where filtered water is not used, it is absolutely essential to use alcohol flushing and prolonged air drying at the end of lists for routine endoscopes and colonoscopes. Alcohol and air drying between cases for routine endoscopy and colonoscopy will be impractical because of time constraints in busy units. Alcohol rinsing between cases for duodenoscopes and bronchoscopes is dangerous because of the potentially disastrous risks of introducing alcohol into the pancreatic duct or bronchi.

4. Where water guns are used, they must be able to be disassembled for cleaning and disinfection.

5. In small units or isolated areas where neither filtration nor regular bacteriological water testing is practical, then alcohol flushing and air drying between each case is an acceptable alternative for routine endoscopy and colonoscopy.

7. RINSING

Rinsing should take place under running water so that all traces of detergent and disinfectant are flushed away. Failure to adequately rinse glutaraldehyde from endoscopes has been reported to cause severe post colonoscopy colitis and may be responsible for some cases of post E.R.C.P. pancreatitis. Static rinsing, i.e. rinsing in bowls of water is not recommended.

The amount of water required to thoroughly rinse an endoscope after disinfection will vary according to the design and length of the instrument. It is unlikely that volumes of less than 150mls of fresh water in each channel will be effective in removing chemical residue.

8. DISINFECTANT

Disinfectants for endoscope reprocessing need to have wide bacterial properties together with the ability to kill relevant viruses including HIV, HBV and HCV. Testing should have been conducted under clinical operating conditions as well as under laboratory conditions. Many disinfectants have either a restricted spectrum of activity or have not been adequately tested.

At the time of writing, glutaraldehyde is the only acceptable chemical disinfectant available in Australia for use in unsealed systems. 2% alkaline glutaraldehyde (e.g. Cidex) or 2% neutral complex glutaraldehyde (e.g. Aidal plus) are recommended.

Soaking time

Effective manual cleaning of the item to be soaked is critical in determining the effectiveness of chemical disinfection.

Endoscopes which are not adequately cleaned will not be adequately disinfected even with prolonged soaking times.

The Gastroenterological Society of Australia and the Gastroenterological Nurses Society of Australia recommend at least 10 minutes soaking in 2% glutaraldehyde at 20°C following the recommended cleaning regimen.
Chemical disinfection must take place in an area with adequate physical controls such as forced air extraction. Soaking bowls must have close fitting occlusive lids. Forced air extraction should extend to the rinsing sink. Post disinfection rinsing should be performed in COLD running water (warm or hot water increases the amount of fumes generated).

**ENDOSCOPY SHOULD NOT BE PERFORMED IN CENTRES WHERE ADEQUATE FACILITIES FOR CLEANING AND DISINFECTION ARE NOT AVAILABLE.**

Staff required to chemically disinfect endoscopes must be provided with education in the safe use of glutaraldehyde and with personal protective clothing which includes impervious gowns (or gowns and plastic aprons), gloves which have been approved for use with glutaraldehyde and face shields (see Occupational Health and Safety).

**9. GENERAL MAINTENANCE**

Leak testing of endoscopes should be performed after use as per manufacturers’ instructions. Failure to detect a leak prior to thorough cleaning and disinfection may result in major damage to the instrument.

Examination of the instrument lens and outer sheath should be performed following each session to detect any signs of cracking or damage. The function of angulation cables should be checked.

Inspection of "0" rings on valves for sign of wear should be performed at the end of each session. "0" rings should be changed when signs of wear are detected. Biopsy caps should be checked for signs of wear and replaced as required.

**10. LUBRICATION**

Lubrication is used to ensure optimal functioning of both endoscopes and accessories. The "O" rings on suction and air/water control buttons require lubrication to prevent the buttons sticking in the depressed position. Traditionally silicone oil supplied with the endoscope has been used. Silicone oils can be either petroleum based or in a water soluble base. There is evidence that both preparations may impair reprocessing[^213]. Biological fluid can be entrapped within oil globules and protected from disinfectant action. The choice is therefore to either take particular pains to ensure complete removal of silicone based lubricants or to use surgical instrument lubricant.

**Recommendation**

(a) Accessory items processed in ultrasonic cleaners should be lubricated with an instrument lubricant following completion of the ultrasonic cleaning. They should then be wiped with a clean, lint-free cloth and allowed to air dry prior to packaging for steam sterilisation.

(b) Where silicone oil lubricants are used for suction and air/water control buttons, they should be applied immediately before use (after chemical disinfection). It is essential to remove lubricant residue to allow germicide contact. Ultrasonic cleaning will remove any small remaining amounts of lubricant.
11. WORK AREAS

Work areas should be planned carefully. The areas should be well ventilated and the cleaning area should include the following:

1. At least one sink designated for the cleaning of instruments, referred to as the “dirty” sink. This should be made of materials which are impervious to solution, such as stainless steel, porcelain or of a plastic bonded material. The sink must be of sufficient dimensions to adequately hold a full length colonoscope without causing the instrument injury, e.g. laundry tub size. The sink should be supplied with running hot and cold water.

2. An area adjacent to this sink where the components of the instrument are removed for cleaning. The “dirty” bench is then suitable for holding instruments awaiting chemical disinfection.

3. An area for disinfection of instrument. In the case of automated disinfectors the dimensions and requirements must be assessed by the make and model of the machine to be installed. For manual disinfection, a container of solution of sufficient dimensions to hold an instrument without injury to the instrument would need to be available. It is preferable that this container be a fixed sink placed under an appropriate fume extraction system. Otherwise a container especially designed for glutaraldehyde disinfection of instruments is available. This must be placed in a fume extraction cupboard.

4. Where an automated disinfector is used, rinsing is performed within the machine. Where manual rinsing occurs, a sink designated for rinsing only clean instruments must be available.
Decontamination Regimens

Introduction

It is known that stored endoscopes may become colonised with vegetative bacteria during storage, especially if the drying process is not adequate157. Unfortunately the complex structure and fine channels of endoscopes preclude absolute certainty that drying processes are always effective. Therefore endoscopes must have a full disinfection process performed prior to use on the day and at the end of the list.

At the end of a list, using 70% isopropyl alcohol to enhance the drying process, the endoscope must be thoroughly forced air dried prior to storage. Methylated spirits is NOT suitable for this process.

1. MANUAL CLEANING

The following steps should be performed immediately following a procedure.

1.1 IMMEDIATELY after each procedure with the endoscope still attached to the light source, grasp the control head. Using a disposable cloth soaked in detergent solution, wipe the insertion tube from the control head to the distal tip. Discard cloth.

1.2 Place distal tip in detergent solution. Aspirate through suction channel - depress and release suction button rapidly to promote debris dislodgement.

1.3 Depress and release air/water button several times to flush water channel. Occlude air button to force air through the air channel.

1.4 Some types of endoscope have air/water channel cleaning adaptors that should be placed in the air/water valve seat at this point as per manufacturers instructions to flush the air channel. If there is no such adaptor the water bottle connector should be removed from the endoscope taking care not to contaminate its end. The endoscope should be removed from the light source and taken to the cleaning area. (If due to local circumstances there is a delay prior to thorough cleaning place the endoscope in a bowl of enzyme solution and soak. Ensure protective caps are applied before immersing in solutions.) IT IS ESSENTIAL THAT THE ENDOSCOPE IS NOT ALLOWED TO DRY PRIOR TO CLEANING AS THIS WILL ALLOW ORGANIC MATERIAL TO DRY MAKING REMOVAL FROM CHANNELS DIFFICULT OR IMPOSSIBLE.

1.5 In the case of video scopes the protective cap over the plug should be applied. Leak test the instrument as per manufacturer’s instructions. WARNING: It is essential that manufacturer’s instructions be followed.

1.6 Remove all valves and buttons. Brush and clean paying particular attention to internal surfaces. Place buttons in an ultrasonic cleaner.

1.7 Place endoscope in enzymatic/detergent solution and using the brushes provided by the manufacturer brush the suction/biopsy channel in all directions. If the brush contains obvious debris it should be cleaned before being withdrawn. Each channel should be brushed until all visible debris is removed. Wash all outer surfaces.

1.8 Using a soft toothbrush, gently clean the distal tip of the endoscope.
1.9 Brush control handles and biopsy port. Brush around valve seats.

1.10 Clean valve seats thoroughly - check that all visible debris has been removed. Use special brushes if provided by manufacturer.

1.11 Fit cleaning adaptors. Thoroughly flush all channels with enzymatic solution.

1.12 Rinse outer surfaces. Flush all channels thoroughly with fresh water. It is essential that all detergent be removed prior to disinfection.

1.13 Purge channels with air to remove rinsing water. Dry outer surface with soft cloth.

1.14 Disinfect as per section 2.

2. MANUAL DISINFECTION

2.1 After manual cleaning immerse endoscope in disinfectant so that the entire endoscope is submerged. Fill all channels with disinfectant so that all air bubbles are expelled. All channel entrances must be under the surface of the disinfectant during this procedure to ensure that no air enters the channel. Remove the buttons and valves from the ultrasound, rinse, dry and then immerse in glutaraldehyde as per 2.2 or autoclave if applicable. It is preferable to have extra supplies of buttons and valves to ensure that adequate cleaning is performed prior to immersion in glutaraldehyde.

2.2 Endoscopes

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<thead>
<tr>
<th>Type</th>
<th>Disinfection Details</th>
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<tr>
<td>SOAK FOR 10 MINUTES IN 2% GLUTARALDEHYDE AT 20°C</td>
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Bronchoscopes

<table>
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<th>Type</th>
<th>Disinfection Details</th>
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<tr>
<td>SOAK FOR 20 MINUTES IN 2% GLUTARALDEHYDE AT 20°C</td>
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IF THE TEMPERATURE IS LOWER THAN 20°C THEN THESE SOAKING TIMES WILL NEED TO BE PROLONGED (ACCORDING TO PRODUCT SPECIFICATIONS)

A timer with an alarm is essential to ensure that accurate soak times are achieved. (Digital timers are more accurate.) A fluid thermometer with digital readout is recommended to constantly monitor temperature of glutaraldehyde solution.
2.3 Purge disinfectant from all channels with air and remove endoscope, valves and buttons from disinfectant, taking care to avoid drips and splashes.

2.4 Rinse exterior of endoscope thoroughly and flush channels with fresh water to remove traces of glutaraldehyde. Rinse all valves and buttons thoroughly.

2.5 Purge all rinsing water from channels.

2.6 If the instrument is being prepared for reuse, remove the cleaning adaptors. Dry exterior surfaces with a soft cloth and reassemble endoscope.

*If the instrument is to be stored do not remove cleaning adaptors and refer to point 3.1.*

3. **AT THE END OF THE LIST**

3.1 Flush all channels with 70% Isopropyl alcohol (approximately 2mls for elevator channels, approximately 20mls for each other channel). If using a multichannel cleaning adaptor the quantities of alcohol may need to be increased.

3.2 Force air dry all channels. Ensure that the air source has a flow regulator and use lower pressure on fine channels. Use bayonet fittings rather than luer lock to attach the air tubing to the cleaning adaptors and fit securely but not tightly - if safe pressure is exceeded the bayonet fitting will give way. Use of excessive air pressure may cause damage to the instrument.

3.3 Ensure that all outer surfaces are dry.

3.4 Check the instrument for any sheath or lens damage. Polish the lens with the cleaner provided by the manufacturer. DO NOT REASSEMBLE ENDOSCOPE.

3.5 Store endoscope (disassembled) in a well ventilated storage cupboard, which permits full length hanging on appropriate support structures.

*Endoscopes should not be stored in transport cases as these may themselves become contaminated.*

3.6 Lubricate all "0" rings on buttons, valves and cleaning adaptors and store separately

4. **ENDOSCOPIC ACCESSORY EQUIPMENT**

The cleaning and disinfection of reusable endoscopic accessories is equally as important as that of the endoscope.

Endoscopic accessories have been implicated in the transmission of infection.

(a) **Cleaning**

As with endoscopes, the cleaning of accessories as a prerequisite to sterilisation is mandatory.

1. All equipment should be immersed in enzymatic detergent immediately following use until cleaning can be performed.
2. The equipment should be dismantled as far as possible and all visible soiling removed.

3. Any spiral coil, hinged or complex structured accessories should be placed in an ultrasonic cleaner and processed according to manufacturers' recommendations. NB Keep hands out and lid on. (Refer Aust. Std 2773)

4. Any fine bore cannulae or tubing accessory items will require thorough flushing with enzymatic detergent. Other accessory items, depending on design, will require a combination of flushing and brushing to clean surfaces.

5. Following cleaning by either of these methods, accessory items should be thoroughly rinsed and dried prior to disinfection, autoclaving or ethylene oxide sterilisation.

(b) Disinfection

In general, accessory equipment used in gastroenterological procedures requires high level disinfection. However, accessories that enter sterile tissue or the vascular system must be sterile. This includes biopsy forceps, injection sclerotherapy needles and all accessories used for E.R.C.P. Where an alternative exists, all non-autoclavable reusable accessories should be phased out.

1. All autoclavable equipment must be cleaned thoroughly prior to sterilisation process.

2. All non-autoclavable equipment should be immersed in glutaraldehyde ensuring all cavities are flushed with glutaraldehyde. The soaking time will depend on whether the accessory item will be required to enter sterile tissue (see section on Disinfection).

Some accessory items require specific comment.

Sclerotherapy needles are difficult to clean and reprocess to a sterile state. Therefore it is recommended that only single use sclerotherapy needles be used.

Water bottles and connectors. These accessory items should be autoclaved at the beginning and end of each session as they have been implicated in the transmission of infection. All non-autoclavable bottles and connectors should be replaced with those that are fully autoclavable.

Where an alternative exists all E.R.C.P. accessory items that are not autoclavable should be phased out.

Dilators are likely to come in contact with tissue that has been abraded or otherwise damaged by the dilation process. They should therefore have undergone high level disinfection immediately before the session. Note the operative field will not be sterile as the patient's own microbiological flora will contaminate the area. Dilatation is also frequently performed using an endoscope that has undergone high level disinfection.
5. REPROCESSING FLEXIBLE BRONCHOSCOPES AND ACCESSORIES

Refer to section on mycobacteria and *Serratia marcescens*. in the section “The Infecting Organisms”:

1. The Center for Disease Control and Prevention recommends that bronchoscopy should not be performed on patients with active tuberculosis unless absolutely necessary.

2. No method will successfully achieve high level disinfection of bronchoscopes unless adequate mechanical cleaning has been performed – *Mycobacterium tuberculosis* survived ten complete disinfection cycles in 2% glutaraldehyde after inadequate cleaning.

3. Automatic disinfectors and bronchoscopes have frequently been colonised with atypical mycobacteria.

4. Flexible bronchoscopes that cannot withstand the process outlined below because of age, design or damage should not be used.

IMMEDIATELY FOLLOWING USE

1. If specimen trap has been used, disconnect from suction line.

2. Aspirate enzymatic/detergent solution through the instrument (approximately 200mls) by depressing the suction button/valve.

3. Using a disposable cloth soaked in enzymatic/detergent solution wipe insertion tube from control handle to distal tip to remove excess secretions and debris.

4. Disconnect the instrument from the suction and light source.

5. Take instrument to cleaning area.

6. **NB If cleaning cannot be performed immediately ensure the instrument is leak tested then leave soaking in enzymatic solution until full cleaning can be performed.**

CLEANING OF INSTRUMENT

1. Perform leakage test in freshly prepared water. Manipulate controls to check action of distal tip and to detect any breaches of the outer skin of the scope when the A rubber is stretched.

2. Disassemble the instrument by removing biopsy cap and suction valve/button.

3. Disassemble suction valve and clean with brushes, then place in ultrasonic cleaner. If using reusable biopsy caps, brush cap and then rinse.

4. Immerse instrument in enzymatic/detergent solution. Using the cleaning brush, brush the suction channel by inserting the brush in the suction port in a downward fashion to the distal tip. Brush until all debris is removed (it may be necessary to clean the brush inbetween accessing channel). Brush the biopsy channel downward to the distal tip. **NEVER BRUSH FROM THE DISTAL TIP UPWARDS. NOTE:** Some twin channel instruments will require brushes of differing sizes.
5. Using a brush, clean both suction and biopsy ports.

6. Using a very soft toothbrush, brush distal tip. do not brush soft exterior sheath of scope. Brush control handle and eyepiece with soft toothbrush.

7. Wipe outer sheath with soft cloth.

8. Attach cleaning adaptor.

9. Flush enzymatic/detergent solution through all channels (approximately 100mls).

10. Flush clean water through all channels (approximately 200mls).

11. Expel water from all channels using regulated air.

12. Place instrument in 2% glutaraldehyde ensuring all external surfaces are in contact with the solution. Flush glutaraldehyde through all channels removing all air from channels. Place suction valve/button and biopsy cap in glutaraldehyde.

13. SOAK FOR 20 MINUTES in a container with a firm fitting lid.

14. Use a timer for accurate measure of soaking times.

**BETWEEN CASES**

1. If the instrument is to be used again for another patient, remove instrument from glutaraldehyde solution and into a sink of sterile/filtered water. Flush all channels with sterile/filtered water to remove any traces of glutaraldehyde.

2. Rinse suction valve and biopsy cap in sterile water and then dry.

3. Attach air connectors to expel water from channels.

4. Pat instrument dry with clean cloth.

5. Reassemble the instrument.

**AT THE COMPLETION OF THE SESSION**

1. Remove instrument from glutaraldehyde and place in a sink of fresh water. Using tap water flush the channels to remove all traces of glutaraldehyde.

2. Insert approximately 20mls of 70% alcohol into the cleaning adaptor.

3. Attach air supply and force air dry the scope.

4. Bronchoscopes should be stored on hangers designed for the purpose, NOT COILED IN CASES. Do not reassemble. Remove all cleaning adaptors.

5. Dry all valves and caps.
ACCESSORY EQUIPMENT

All equipment used for taking samples and specimens must be sterile. Cytology brushes are single use, as are specimen traps. A variety of forceps are suitable for use via the biopsy port. Take care to ensure the diameter of such equipment is suitable for insertion in the small channel. NEVER FORCE FORCEPS OR BRUSHES IN THE CHANNEL AS THE CHANNEL WILL BECOME DAMAGED.

All forceps must be sterile. The most important step in the sterilisation process is that the equipment must first be clean. Forceps should be placed in an enzymatic solution immediately after use BEFORE secretions can dry on the equipment.

1. The forceps, cups and wire coil must then be cleaned manually using a soft toothbrush.

2. Place equipment in ultrasonic cleaner and process according to manufacturers’ instructions.

3. Rinse equipment.

4. Dry thoroughly.

5. Package and label equipment.

6. Forward to CSSD.

6. VARIATION IN CLEANING AND DISINFECTION REGIMENS DEPENDING UPON THE SUPPOSED INFECTIVE STATUS OF THE PATIENT

A number of surveys have shown that the practice of varying the cleaning and disinfection regimen according to the supposed infective status of the patient is widespread. Reynolds et al. reported that in up to half the endoscopy units surveyed in Massachusetts, hospitals changed their reprocessing techniques after use in patients with known HIV infection, tuberculosis or hepatitis. Common practices include using ethylene oxide “sterilisation” or prolonging chemical immersion times for endoscopes used in patients with these diagnoses. Such an approach is totally unscientific and illogical. Many patients who have these disorders and do not know or conceal such knowledge will be subjected to endoscopic procedures. It is therefore totally unacceptable to have a cleaning and disinfection schedule that does not effectively deal with such unrecognised cases. By logical extension, if the cleaning and disinfection regimen is adequate to deal with unknown cases, then it is also adequate to deal with known cases. Conversely, the use of special precautions in known infected cases clearly implies that the regimen used under routine circumstances is thought to be inadequate to prevent transmission of these diseases. There is clear, adequate evidence to show that the cleaning and disinfection schedule recommended in this review is adequate to prevent the transmission of infectious disorders including HIV infection, hepatitis and tuberculosis. There is therefore NO JUSTIFICATION to alter the cleaning and disinfection regimen if patients are known to have these disorders.

It must be noted these statements apply to common pathogens such as human immuno deficiency virus, hepatitis viruses and bacteria. Special and unusual hazards do exist. The problems associated with modified Prion Protein diseases (Creutzfeldt Jakob Disease and other spongiform encephalopathies) are considered on pages 18 and 19. These agents are highly resistant to conventional forms of microbiological destruction and the containment measures outlined in the section should be followed.
There is no evidence that *Mycobacterium tuberculosis* can develop adaptive chemical resistance. A special problem with *Mycobacterium tuberculosis*, however, exists in relation to staff and patient cross infection from contaminated aerosols. As noted in the section on *Mycobacterium tuberculosis*, the Centre for Disease Control strongly recommends that bronchoscopy is not undertaken in patients with known active tuberculosis. Where open cavitating tuberculosis exists the risk of aerosol spread is extremely high. Persistent and explosive coughing is frequent during and following bronchoscopy and the risk of mycobacteria containing aerosols is significant even with closed tuberculosis. Appropriate precautions in the examination room will include negative air pressure ventilation with operating theatre levels of air exchange together with appropriate personal protective measures for the staff.

Adaptive chemical resistance to a wide range of disinfectants has been convincingly shown for atypical mycobacteria and problems associated with the decontamination of automatic disinfectors are considered on page 52.

7. REUSE OF MEDICAL DEVICES LABELLED ‘SINGLE USE ONLY’

The annual cost to the United States health services alone of devices labelled ‘Single Use Only’ is estimated to exceed three billion dollars. It is therefore hardly surprising that in a climate of progressive fiscal restraint, health care facilities will attempt to restrain costs by reusing devices labelled ‘Single Use Only’. The safety, ethical and legal issues involved in such reuse have proved to be complex and divisive, various stakeholders viewing the problem from one perspective only.

Major physical issues in reprocessing ‘Single Use Devices’ are clearly stated in the compliance policy guide of the F.D.A.:

1. That the device can be adequately cleaned and sterilised.
2. That the physical characteristics or quality of the device will not be adversely affected; and
3. That the device will remain safe and effective for its intended use.

Less clear are the ethical and legal issues raised in reprocessing. The underlying issues revolve around the opposing arguments of utilitarianism and contractarianism. Does the maximisation of benefit to society as a whole from the more efficient use of medical financial resources outweigh a small but essentially unquantifiable increase in risk to the individual patient in whom a ‘single use only’ device is reused?

Not surprisingly where the underlying ethical issues are complex and inconclusive, the legal position is even more clouded. The exact legal position will vary from country to country and even from jurisdiction to jurisdiction within a country.

The overall legal position is likely to be that most actions for redress in the event of injury related to reuse of a ‘single use only’ device will be in negligence. Clearly the contravention of specific laws within a particular country will also be relevant.

In general, arguments of negligence will turn on the questions of Duty of Care and Informed Consent. Under the Duty of Care concept a practitioner is obliged to provide a standard of care not substantially less than provided by a prudent body of his peers. The High Court of Australia has recently extended the Duty of Care concept such that the Court may determine what is an appropriate standard of care. It is necessary for an institutional practitioner using a ‘single use only’ device to be able to demonstrate product efficacy and safety. This may be by either using a reprocessing technique that is identical to a process validated in existing medical literature or to have carried out a rigorous development testing and validated reprocessing protocol.
Surprisingly there is relatively little literature describing acceptable validated reprocessing protocols for the majority of ‘single use’ devices. After an extremely exhaustive review, E.C.R.I.\textsuperscript{222} (an independent non-profit health service research agency with the W.H.O. status of a collaborating centre) could only conclude “E.C.R.I.’s review and analysis of published clinical studies concludes there is no clear evidence that reuse of ‘single use’ medical devices is either safe or unsafe for patients.”!

Institutions proposing to reuse ‘single use only’ items will face the necessity of developing and validating protocols which can ensure the safety and efficacy of reprocessed items.

Endoscopists have until recent years dealt with these problems with the convenient but highly unsatisfactory device of simply ignoring them. Major problems remain in the reprocessing of endoscopes themselves, let alone accessory devices. Fortunately recent advances in design and manufacture of accessories have resulted in significant improvement. Biopsy forceps can now be autoclaved and there can be no justification for failing to use either disposable or sterilised reusable biopsy forceps\textsuperscript{232-237}. Relatively low cost disposable items are now available for a number of other accessories where clinical usage/design mitigate against effective reprocessing (e.g. endoscopic injecting needles). The main area of debate in the reuse of ‘single use only’ items in endoscopic practice centers around the relatively expensive E.R.C.P. accessories, particularly catheters, sphincterotomes, guidewires and balloons. Fortunately for the majority of these items, device failure during operation is unlikely to have major clinical consequences. Major debate therefore centers around the efficacy of cleaning and sterilisation\textsuperscript{202}.

The available literature provides no clear evidence that reprocessing can be achieved safely or that there is significant cost benefit. The prudent course appears to be either not to reuse items that are labelled ‘single use only’ or to do so under the strictly controlled conditions outlined above.

The above comments refer to equipment where there is at least a reasonable basis for labelling ‘single use only’. Unfortunately there are a number of items labelled in this way for which there appears to be no real justification. An example would be polyp traps. These devices can, in fact, be satisfactorily cleaned and disinfected or even cold sterilised by prolonged immersion in chemicals. However, it is difficult to see why high level disinfection or sterilisation would be necessary since the polyp trap is usually only in the suction line for a relatively brief period with a positive suction flow away from the endoscope at all times. A number of other examples of abuse of this labelling are apparent.

Given the enormous financial implications, discussions about reprocessing of ‘single use only’ devices should not simply be abandoned. Manufacturers should be encouraged to develop reusable products, but since the cost of research and development is substantial, incentives such as preferred purchasing options are necessary. Device manufacturers should be encouraged to become involved in reprocessing of their own products. They are usually in the best position to estimate the reprocessing requirements and limitations of the product. Governments are unlikely to become active participants in third party commercial reprocessing of ‘single use’ devices since in many countries this is likely to expose them to the full legal requirements imposed on manufacturers. Government support for research and development for third party reproprocessors may be necessary if manufacturers are not prepared to become involved in reprocessing their own devices.
Endoscopic Disinfecting Machines

Machines designed to disinfect and rinse endoscopes have been available for more than 15 years but have been slow to gain universal acceptance as a variety of serious and even fatal infections have been traced to various defects in automatic disinfectors. A survey of practices in the United States reported in 1992 showed that mechanised disinfection was used in almost half of the endoscopy centres surveyed. The same report documented a widespread lack of knowledge of the potential problems of contamination associated with automatic processors. This is despite extensive literature documentation of these problems. Recently developed machines have corrected many previous design faults. However, many of the claims are not supported by controlled studies in peer reviewed journals. Rather they rely on in-house data or reports from commercial testing laboratories.

The perceived advantages of disinfecting machines include:

- Standardisation of endoscope reprocessing.
- Reduced exposure of staff to chemicals (particularly glutaraldehyde).
- Reduction in staff time spent on disinfection.

NONE OF THE CURRENTLY AVAILABLE MACHINES NEGATE THE NEED FOR THOROUGH MANUAL CLEANING. THIS IS AN ESSENTIAL PREREQUISITE TO DISINFECTION. CLAIMS BY MANUFACTURERS OF SOME MODELS OF AUTOMATIC ENDOSCOPE DISINFECTORS THAT MANUAL PRE-CLEANING IS UNNECESSARY ARE NOT SUPPORTED BY PUBLISHED LITERATURE IN RESPECTED PEER REVIEWED JOURNALS.

MACHINE DESIGN AND PRINCIPLES

The number of automatic disinfecting machines available is increasing rapidly. Numerous machines are being promoted, often with relatively scant evidence of long term safety and efficacy. The following are ideal principles and design features that should underlie the design and use of automatic disinfectors:

1. The machines will rarely show contamination when new. Unfortunately this is when most machines are tested. Problems with bacterial contamination rarely become apparent in machines before six months and become progressively more likely as the machine ages. "Automatic disinfectors have a sorry history with many past models having clear and obvious defects which should have led to the confident prediction of serious contamination. Modern processors are more sophisticated and testing of newer models rarely reveals contamination. However, the ability of bacteria to outwit should not be underestimated. Increasing wear and age reveals unsuspected defects. Biofilm, valve failure, surface irregularities, fissuring, filter failures and chemical familiarity all offer colonisation opportunities for ever vigilant bacteria."

2. Water Supply: Machines should be plumbed into the water supply rather than use manual filling. It may be necessary to install pre-filters, i.e. filters in the water supply prior to its entry into the automatic disinfecter. Fresh water should be used for each cycle to avoid disinfectant contamination of rinse water. Water quality should be monitored and filters instituted if necessary. If duodenoscopes or bronchoscopes are processed in the machine, membrane cartridge filtration of 0.2micron or equivalent alternative water treatment is mandatory. Once filter systems are installed they in turn must be regularly serviced and monitored. It is all too easy for filters themselves to become a source of contamination.

43.
3. Fume Containment: Provision should be made for the extraction of disinfectant fumes from within the machine or the machine should be contained within a fume extraction hood.

4. Disinfectant Supply: Machines which use a concentrated solution and in-use dilution for a single cycle (e.g. STERIS system) avoid the problem of dilution of the disinfectant with rinsing water. Machines which contain a tank of disinfectant for re-use should be monitored for disinfectant concentration to determine appropriate disinfectant change schedules. **Machines which require filling of a disinfectant reservoir must incorporate a pump mechanism to obviate the need for pouring of solutions into the machine.**

5. Cycle Counter: Visual display and a permanent record of the cycle number should be available to indicate the appropriate time for disinfectant change. Automatic recording of disinfection activity is desirable.

6. Self-disinfection: All machines should have a cycle for auto-disinfection. Unfortunately this term is used loosely and in many machines the so called “auto-disinfection cycle” does not extend to all parts of the machine which may allow significant contamination to develop. It is preferable that the auto-disinfection cycle should use or certainly be capable of using a disinfectant alternative to that which is routinely used in the reprocessing cycle. A number of organisms including atypical mycobacteria (particularly *Mycobacterium chelonae*) can become extremely resistant to glutaraldehyde\(^{22,217}\). Elimination of such colonising organisms may require purging of the whole system with alternative agents including chlorine-releasing disinfectants, peroxide compounds or absolute alcohol.

7. Drying: A drying cycle using filtered air should be complemented by a facility that irrigates the channels of the endoscope with alcohol.

8. Leak Testing: Machines should perform leak testing of the endoscope at least once during the reprocessing cycle.

9. Warning Systems: Audible warning alert should be incorporated for the detection of channel blockage preventing adequate channel perfusion of disinfectant solutions, water filter blockage, leakage detection.


11. A heating facility allows for lower in-use concentration of disinfectant and shorter contact time. The temperature should be monitored if heated disinfectant is used in the machine.

12. Individual Channel Perfusion: Machines which are to be used for reprocessing duodenoscopes must allow for the differential pressures required to use the widely differing sized channels. The forceps elevator channel in duodenoscopes is a particular problem because of the extremely fine bore.

13. Maintenance: A maintenance schedule which ensures tanks, pipes, strainers and filters of both the machine and water treatment system are kept free of biofilms and other deposits should be instituted.

14. Strict bacterial monitoring of disinfecting machines and endoscopes is essential wherever endoscope reprocessing machines are used. Machines which are shown to be contaminated should not be used until cleaned and proven to be microbiologically safe (see Microbiological Testing of Endoscopes).
Proof of Process

Quality control measures are accepted critical processes in the provision of high quality goods and services in all business areas.

In the health field, quality control is fundamental to the delivery of safe and effective clinical services. Endoscopy is hindered by the inability to use sterilisation techniques with clearly defined end points (e.g. steam sterilisation) in the reprocessing of endoscopes.

Several instances of multiple transmission of serious viral infections as a result of medical procedures have caused public, legal and governmental concern. This has provided an added stimulus to develop quality control processes in the reprocessing of endoscopes and accessories.

Experience in industry shows that processes that have clearly defined progress points can successfully develop automated systems. Where defined progress points do not exist then education is a more successful option. In numerous parts of this manual it is stressed that cleaning is the critical part of any successful endoscope and accessory reprocessing protocol. Unfortunately it is difficult to automatically record progress points in the cleaning system. For this reason, GENSA and GESA are introducing a formal training and certification process for those involved in endoscope and accessory reprocessing. In contrast, many aspects of the disinfection process can easily be subjected to automatic recording of important parameters.

The purposes of quality control processes outlined below are:

1. To ensure that those reprocessing endoscopes and accessories have a clear understanding of the important principals of reprocessing and to fully understand each of the numerous steps necessary in reprocessing.

2. To record measurable parameters such as disinfection immersion times, disinfection concentration etc.

3. To ensure that a record exists so that appropriate retrospective linkage analysis can be undertaken. Some examples of the importance of these records include:

   (a) Investigation of possible transmission of viral diseases by endoscopy. It is critical to be able to identify the endoscope used in the infected patient; to be able to identify the patients endoscoped with that instrument before the index case and after the index case; to be able to demonstrate that the instrument was cleaned by a qualified person and subject to a disinfection cycle where adequate parameters such as time, concentration and temperature were used (see section on investigation of possible endoscopic transmission of viral diseases).

   (b) The interpretation of cultures from endoscopes. Various examples are given in the section on bacteriological surveillance of endoscopes. A further example might be where low levels of vegetative bacteria seem to be randomly recovered from a variety of endoscopes. Linkage analysis may show that endoscopes with positive cultures are only occurring when a particular person cleans the endoscope. Clearly this would be cause for retraining of that person.
The type of information required is not limited to but includes the following:

1. Date of procedure.
2. Name of patient (including relevant identification such as date of birth, UR number or address). This information could be formatted on a facility label.
3. Instrument and serial number/code linked, i.e. this means that the particular endoscope used to examine a patient is specifically recorded.
4. Order of patients examined on the list.
5. Signature of the person who manually cleaned the instrument.
6. Signature of the person who rinsed the instrument.
7. Signature of the person who disinfected the instrument.
8. Signature of the person who rinsed the instrument.
9. Signature of the person who tested the strength of the chemical disinfectant.
10. Signature of the person who tested the temperature of the chemical disinfectant.
11. Signature of the person who timed the soaking of the instrument in a chemical disinfectant.

In addition to the above, a register of the batch number of the chemical disinfectant and the date it was decanted into the tank, changed or topped up should be maintained.

Many units will have some or all of the above information recorded in a variety of locations ranging from patient chart to daily register. It is important that a unit based record is kept regardless of whether the information is in the patient’s chart. Such a register should be maintained in the unit according to each unit’s policy.

In view of the possible litigation involved, it is essential that the person/s responsible for reprocessing of endoscopes sign their name following completion of each task. The use of automated machines still requires the instrument to have been manually cleaned prior to the disinfection cycle. It is important that the person who commences each phase of the process completes that particular phase. In situations where more than one person would perform part or parts of a phase in the manual cleaning process, then the person who deems the instrument to be fully cleaned must sign the register. It is therefore recommended that the full manual cleaning of an instrument be performed by one person only or that if a change in personnel occurs that the process be recommenced to completion. The person responsible for soaking the instrument or connecting correctly to an automated machine would then be deemed to have checked the strength of the solution, the temperature and that all channels and external surfaces are in contact with the chemical disinfectant.

Rinsing the endoscopes free of chemical disinfectants to a biologically inert level is another critical phase of the cleaning and disinfection process\(^{361-294}\). The person responsible for rinsing the instrument free of chemical disinfectant will need to sign the register.
**Accessories**

Should accessories be traceable? The following principles should be followed:

1. Accessories which breach sterile surfaces and are difficult to reprocess, such that sterility cannot be regularly achieved, should be single use only, e.g. sclerotherapy needles.

2. Accessories which breach sterile surfaces, are not labelled ‘single use only’ and have documented validated reprocessing systems need only standard indicators, i.e. cleaning by an appropriately certified nurse and indicator evidence of sterilisation, e.g. biopsy forceps. They need not be individually traceable.

3. Accessories which breach sterile surfaces and **ARE** labelled ‘single use only’ require an institutionally validated reprocessing protocol (see ‘single use only’ section) and should be individually traceable.

Each unit/facility is encouraged to develop a register suitable to their particular needs. The sample register as used at P.A.H. Brisbane is provided as an example which may be used in whole or in part, provided that all the principles and information are readily accessible and traceable. Computer printouts from automated machines will require either modification or be used within the register.
# Daily Validation Register

## Glutaraldehyde Concentration

<table>
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<th>Date:</th>
<th>Time:</th>
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### Glutaraldehyde

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<th>Sink 1</th>
<th>Sink 2</th>
<th>Sink 3</th>
<th>Sink 4</th>
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<tr>
<td>Batch No.</td>
<td>Plus</td>
<td>Expiry date</td>
<td>Date of 1st use</td>
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<td>Batch No.</td>
<td>Plus</td>
<td>Expiry date</td>
<td>Date of 1st use</td>
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Signature _____________________

## Ultrasonic Validation after 10 minutes

Pass signature ______________

Fail signature ______________

## Terminal Disinfection

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<th>Air Guns and Tubing</th>
<th>Signature</th>
<th>H₂O Guns and Tubing</th>
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Signature _____________________

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48.
# Daily “Proof of Process” of Scope and Accessories

<table>
<thead>
<tr>
<th>Name</th>
<th>Scope number</th>
<th>Cleaned by</th>
<th>Rinsed by</th>
<th>Glutaraldehyde</th>
<th>Final Rinse by</th>
<th>Accessory Number</th>
<th>Confirmed as sterile &quot;S&quot; or Disinfected &quot;D&quot;</th>
<th>Cleaned by</th>
<th>Ultrasonic for 10 min</th>
<th>Rinsed by</th>
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49.
# Department of Gastroenterology & Hepatology

## Register of Staff involved in Endoscope and Accessory Reprocessing

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<tr>
<th>NAME</th>
<th>SPECIMEN SIGNATURE</th>
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Investigation of Possible Viral Transmission by Endoscopy

The clear evidence of Hepatitis C transmission by endoscopy in France (see Hepatitis C section) together with a series of medically acquired serious viral infections has raised public concern. Increasingly patients will raise the possibility of whether serious viral diseases had been acquired as a result of endoscopic procedures. A number of such claims have already been made in Australia and elsewhere. The aim of this section is to provide general advice for endoscopy units when patients raise the possibility that an endoscopic procedure undergone in that facility has been the source of an acquired viral disease. The most likely viruses involved are Hepatitis C, Hepatitis B and HIV. In some cases these claims will be opportunistic seeking financial gain or seeking to divert attention from the real source of infection. However, it is important to realise that in some patients the source of infection will be genuinely unknown and these patients may sincerely believe that endoscopy is the most likely cause of their disease. If your unit has followed the recommendations laid down in this manual then it is extraordinarily unlikely, indeed it will be unique, if your unit has transmitted a serious viral disease by endoscopy. We would therefore recommend:

1. It will be in the best interests of the patient, public health in general, the endoscopy community and your own unit if a prompt, thorough, competent and decisive investigation is undertaken without delay.

2. It is NOT your role to attempt to determine other possible sources of a patient’s infection!

3. Do NOT conduct the investigation yourself. You are likely to be involved in emotive disputes regarding the source of infection and your investigation will lack the credibility of an independent body.

4. Recognize that a possible conflict of interest exists if the patient is under your continuing care and you have a financial or controlling interest in the centre.

5. In most cases the best independent authority will be the public health unit of your State Health Department who will be able to provide appropriate proforma. You may or may not wish to suggest to the public health unit that they take advice from an independent microbiologist nominated by you.

6. In practice an appropriate protocol will require:

   (a) The endoscope used on the patient in question should be easily and reliably identified.

   (b) The endoscope should be inspected by the manufacturer for defects.

   (c) Patients on whom this instrument has been used following the index case should be tested for the viral disease in question.

   (d) Patients endoscoped before the index case should also be tested. This will usually involve the three patients examined prior to the index case.

   (e) Staff should be tested for the appropriate virus infection.

   (f) An independent assessor will observe the endoscope reprocessing protocols.

   (g) The anaesthetic technique will be assessed.
(h) Accessories which penetrate sterile tissue (e.g. biopsy forceps, polypectomy
snares, sphincterotomes) should be sterile.

There is always the possibility of a Scottish verdict – not proven either way. In general
the speed and thoroughness with which you respond to any complaint increases the
likelihood that a definitive result will be obtained. If you have followed the recommended
protocols then this will almost certainly be negative and will be of benefit to the facility,
yourself, endoscopy in general and presumably the patient.

The importance of prompt and thorough investigation is demonstrated by the response to
a statement in the Royal Australasian College of Surgeons’ policy document “Infection
Control in Surgery” stating, “There is a report from Gosford, New South Wales of a
patient probably acquiring Hepatitis C from colonoscopy.” This statement has been
widely reported in the public and medical press and has simply raised public and
professional anxiety without any definite foundation. We would again stress that the best
interests of all involved are best served by a prompt, thorough investigation that comes
to a definite conclusion.
Microbiological Testing of Endoscopes (Including Bronchoscopes) and Automatic Endoscope Disinfectors

1. INTRODUCTION

Appropriate bacteriological surveillance of endoscopes and automatic processors has proved one of the most difficult and controversial areas of infection control in endoscopy. It is therefore appropriate to state the principles involved together with the details of sample acquisition, processing and interpretation.

Microbiological contamination of endoscopes may occur if:

1. Reprocessing has been inadequate or otherwise deficient.
2. The endoscope is damaged.

Reprocessing deficiencies may occur during:

1. Manual cleaning. This will include all aspects of proper cleaning, from allowing biological material to dry on or in the endoscope through failure to carry out each of the numerous cleaning steps properly. Deva et al\(^5\) has shown that failure to brush even the short segment of the biopsy channel between the suction button and the biopsy forceps port resulted in persistent viral and bacteriological endoscope contamination even after an otherwise adequate manual reprocessing and full disinfection. The colonoscopic transmission of Hepatitis C in France may well have resulted from failure to brush colonoscope channels adequately.

2. Disinfection failures may occur because of the use of inappropriate disinfectants, inadequate immersion time or more frequently the use of contaminated automatic processors.

Endoscope Damage:

It is not possible to adequately inspect the internal channels of endoscopes. Cracking, splitting, fissuring, joint disruption, actual channel wall holes can all be the source of bacterial contamination within the scope which can be difficult to impossible to detect by routine inspection and testing. BACTERIOLOGICAL SURVEILLANCE OF ENDOSCOPES IS FREQUENTLY THE ONLY MEANS OF DETECTING THESE PROBLEMS AT THIS TIME.

2. TESTING SCHEDULES

Whether or not bacteriological screening of standard endoscopes and colonoscopes needs to be performed and if so how frequently remains controversial. On the other hand MICROBIOLOGICAL MONITORING OF DUODENOSCOPES IS ESSENTIAL. The presence of potentially transmissible bacterial pathogens following inadequate cleaning is usually accompanied by the inadequate removal of other enteric bacteria. Thus microbiological monitoring of endoscopes should be viewed as an indirect marker of adequacy and completeness of the cleaning and disinfection process, i.e. is a marker of rigorous adherence to the recommended protocol and also as a measure of structural integrity of the instrument. Assessment should focus on the acceptability of the total number of organisms remaining.
Routine taxonomic identification is not indicated except where microbiological failure persists after a rigorous review of compliance with both cleaning and disinfection protocols, after review of the structural soundness of the endoscope or where clinically recognised cross-infection is apparent. Numerous studies document the transmission of infection by contaminated duodenoscopes during E.R.C.P. (see E.R.C.P section). In many of these outbreaks the endoscopy units involved were unaware of the instrument contamination and the serious clinical infections being caused. The outbreaks were frequently overlooked for prolonged periods and only came to light as a result of investigation of a series of infections with similar or unusual organisms.

WHAT TO LOOK FOR

Viruses

It is frequently asked why microbiological surveillance does not extend to viruses. The principles involved here are:

1. Viruses can only proliferate within cells. Therefore proliferation in the internal channels of endoscopes or in automatic disinfectors does not occur.

2. Deva et al have shown that bacterial contamination after reprocessing is an accurate reflection of viral contamination. Where bacteria remained on or in an endoscope after reprocessing there was also frequently remaining viral material. Conversely however, in no case where all bacterial contamination had been removed were remaining intact viruses demonstrated.

3. The detection of intact infective viruses is extraordinarily complex, prolonged and expensive, indeed, prohibitively expensive for routine surveillance purposes. Many viruses, e.g. HBV, cannot be cultured in vitro. The detection of viral nucleic acid by PCR techniques (see Hepatitis C section) certainly does not necessarily reflect the presence of intact infective viral particles.

Bacteria

Bacterial cultures should be directed to the detection of:

- **Endoscopes and Colonoscopes**
  Common pathogens, including pseudomonas, klebsiella, proteus, E coli and salmonella.

- **Automatic Processors and Bronchoscopes**
  Pseudomonas, similar organisms and atypical mycobacteria.

Previous recommendations that other common tap water contaminants, including legionella and cryptosporidia should be looked for do not appear to be clinically useful and are difficult and expensive. We do not recommend routine cultures for these organisms.
3. RECOMMENDATIONS

Because of differential risks of infection transmission, recommendations vary with both the proposed use of endoscopes and with the method of disinfection and cleaning:

1. Disinfecting machines and endoscopes processed in this way should be monitored every four (4) weeks.

2. Duodenoscopes and bronchoscopes should be monitored every 2-4 weeks.

3. All other gastrointestinal scopes should be routinely monitored every four months.

4. If major changes are made in the Endoscopy Unit personnel responsible for cleaning or if there is a clinical suspicion of cross-infection related to endoscopy, then further microbiological screening should be undertaken in conjunction with a Clinical Microbiologist.

4. MICROBIOLOGICAL TESTING PROTOCOLS

These protocols are primarily instituted to detect an increased residue of enteric bacteria following routine cleaning and disinfection which represents a surrogate marker of inadequate cleaning or of structural damage to the channels of the endoscope.

Method of Sampling

1. 10mls of sterile water (or Ringer's solution) is withdrawn from a freshly opened bottle using a sterile needle and syringe and put into a sterile universal container.

2. A second 10mls of sterile water (or Ringer's solution) is flushed to fill the channel to be sampled.

3. A sterile endoscope brush is passed down the biopsy channel, withdrawn and swirled in the universal container containing the sterile water (or Ringer's solution). The brush will need to be handled using sterile gloves. The endoscope brush should be sterilised by autoclaving or gas sterilisation.

4. A further 10mls of sterile water (or Ringer's solution) is flushed through all of the channels (air-water, suction) by using a sterile syringe. The rinse fluid (20 to 30 mls) is collected in another sterile universal container.

5. Both containers are labelled and sent with a request form detailing the following:
   
   a. Type of scope sampled and serial number.
   
   b. Name of person to whom report should be sent.
   
   c. Test request - Endoscope routine culture.

Note:
Organisms (especially pseudomonas) can multiply in fluids. Therefore it is essential that the sample is promptly processed after collection. If there is likely to be any delay the sample should be refrigerated. Any delay, such as samples being collected in the late afternoon and not processed until the following day, may lead to erroneous results.
Laboratory Procedure - Infection Control

1. The collected sample is centrifuged down to 1ml.

2. All specimens – blood agar and MacConkey agar under aerobic conditions only.

3. Semi quantitation of bacterial growth should be performed, e.g. no growth, 10 to 100 colonies, 100 to 10,000 colonised, > 10^4 colonies.

5. **INTERPRETATION OF CULTURES**

Each endoscopy unit in conjunction with a clinical microbiologist must set its own threshold for the initiation of action if cultures are positive. Some examples are given below:

1. Low numbers of environmental type organisms, e.g. *Staph epidermis*, may be encountered not infrequently. These are most likely to represent collection process contamination rather than a significant problem with the disinfection or cleaning process. The most appropriate initial response is to review the sample processing technique to reduce the chance of contamination.

2. A growth of *Pseudomonas spp* from a duodenoscope or an automatic processor that processes duodenoscopes would be cause for serious and immediate concern. This is a high risk clinical situation and the immediate responses would include removing the automatic processor and duodenoscope from service, careful culturing of the automatic processor to see if it is the source of contamination, careful inspection of the duodenoscope for defects and repeated cultures after manual reprocessing to see if infection persists and clinical follow up of patients recently undergoing E.R.C.P. and related procedures with that duodenoscope.

3. Significant numbers of enteric organisms, e.g. *E coli* or *Enterococcus faecalis* being recovered from one instrument only. This suggests that there is a mechanical defect in the instrument and careful inspection with replacement of the insertion tube if no other defect can be identified.

4. Significant or borderline numbers of enteric organisms such as *E coli*, *Enterococcus faecalis* being recovered from a variety of instruments within the unit. This is strong evidence of inadequate reprocessing. It is most likely to be due to defects in the manual cleaning program. Much less likely is a problem in an automatic disinfecter, (e.g. worn valves, serious biofilm accumulation etc). Appropriate response here would be a detailed review of all staff’s cleaning and disinfection techniques, if necessary by an independent assessor.

5. Culture of *Mycobacterium tuberculosis* organisms from a flexible bronchoscope. This is a potentially serious problem. Responses would include removal of the bronchoscope from service, mechanical review of the instrument by the manufacturer, review of any automatic disinfector used including detailed cultures and clinical surveillance of patients recently bronchosoped with that instrument.

6. Growth of *Mycobacterium chelonae* from a bronchoscope. It is almost certain that this will prove to be due to a contaminated automatic disinfector that needs to be taken out of service and decontaminated.

7. **ANY** isolation of salmonella or shigella should cause concern.
6. MICROBIOLOGICAL SURVEILLANCE OF AUTOMATIC DISINFECTORS

The method of sample collection for automatic disinfectors will vary depending upon the design of the individual machine. It is therefore appropriate to seek advice from the manufacturers or consult with your hospital clinical microbiologist. Commonsense would suggest that the most appropriate point of the machine to sample is the attachment of the machine to the endoscope. For machines with a single point of attachment (e.g. Medivator) this is relatively simple. Where there are multiple endoscope connections the problem becomes more complicated. Further, it is essential to know the design of the machine to determine which is the optimum part of the cycle to collect the sample. In most cases this will be in the rinsing cycle. Early detection of machine contamination is best effected by a concentration process. For example, a technique which works well with the Medivator is to connect a sterile sealed Millipore filter to the outlet of the machine where it normally attaches to the endoscope and to cycle at least 200ml of fluid through the filter in the rinse cycle mode. The disc can then be removed and plated directly. Since the principal contaminants of automatic disinfectors are Pseudomonas and related species and various forms of atypical mycobacteria, cultures should be directed towards these organisms.
Occupational Health and Safety in the Endoscopy Workplace

1. INTRODUCTION

The relevance of a chapter on Occupational Health and Safety in the Endoscopy Workplace in a manual on “Infection Control in Endoscopy” may be questioned. In previous editions this chapter was inserted because of the demonstrated lack of appropriate concern by administrators for such important topics as glutaraldehyde sensitivity and immunisation against Hepatitis B. We have decided to retain the chapter because this document is widely available in endoscopy units and the chapter provides some simple guidance. It does not purport to be an extensive or comprehensive review of occupational health and safety issues.

2. CHEMICAL AND HAZARDOUS SUBSTANCES EXPOSURE

A. Glutaraldehyde

(a) Structure
Glutaraldehyde is 1,5-pentanedial. It is an aliphatic dialdehyde that undergoes standard aldehyde chemical reactions to form acetal, cyanohydrins, hydrazones and bisulphite complexes. It reacts with proteins by forming cross-linkage reactions. Glutaraldehyde concentrations in air may be determined by a number of methods. A readily available commercial instrument is the hand held glutaraldehyde meter, which has a detection range from 0.05-5ppm v/v. THE INSTRUMENT, HOWEVER, IS SUBJECT TO INTERFERENCE FROM A VARIETY OF CHEMICAL COMPOUNDS INCLUDING ALCOHOL AND OTHER ALDEHYDES (as well as colognes and perfumes), AND WHEN USED IN THE PRESENCE OF THESE WILL GIVE FALSELY ELEVATED READINGS.

Caution is needed in the interpretation of readings. Estimation of isolated values is not as important as cumulative exposure over the course of a working day.

(b) Occupational Health
A wide variety of animal and human studies are available. Many of these are summarised in the full public report, Glutaraldehyde -Priority Existing Chemical No. 3 by the National Industrial Chemicals Notification and Assessment Scheme. (Australian Government Publishing Service, Canberra, 1994)

The national exposure standard for glutaraldehyde is 0.1ppm. v/v (Peak Limitation)\textsuperscript{257}. It should be noted that industrial health problems have been reported with exposure concentrations below 0.2ppm\textsuperscript{258,259}. It is difficult to be certain whether peak values are exceeded from time to time, but go undetected. Documented adverse human health effects include respiratory, nasal and skin problems. Headache, nausea, lightheadedness, palpitations and tachycardia have also been reported, although the association with these remains less certain.

Eye Irritation
Accidental splashes with glutaraldehyde may cause severe irritation, pain and light sensitivity. Conjunctival and corneal irritation from vapour exposure occur frequently\textsuperscript{258}.
Staff members wearing contact lenses should consult with their ophthalmologists regarding the suitability of their lenses in the endoscopy setting. Some lenses may become discoloured or impregnated with glutaraldehyde and cause eye irritation.

Respiratory Irritation
Respiratory irritation, including irritation of the nose and throat have been commonly reported. Chest tightness, coughing, asthma and apparent initiation of asthma have also been reported\(^{258-265}\).

Skin Sensitisation
Contact dermatitis from skin sensitisation has been reported on numerous studies\(^{265-270}\). It is important to note that this contact dermatitis may be associated with deep skin fissuring and cracking, resulting in an increased susceptibility to blood contact infections (e.g. HIV).

Epidemiological studies have not shown any correlation between miscarriage or foetal deformity and glutaraldehyde exposure\(^{271,272}\).

Clearly, there is a wide variation in the susceptibility to the toxic effects of glutaraldehyde. It is important to keep exposure to the minimum possible, since once allergic response occurs, even exposure to minute vapour concentrations may precipitate symptoms.

(c) Safety Measures

Glutaraldehyde has been a major cause of the occupational health problems outlined above. In many instances this has been due to the failure to provide adequate fume containment and ventilation systems. Features of an effective fume cupboard for Glutaraldehyde use include\(^{296}\):

- Air directed from the front access of the cupboard, across the work area and extracted through a baffle at the rear of the cupboard.
- A fan above the work area with air extracted via ducting to a safe location outside the building.
- A face velocity of 0.5-1.0 m/sec at the front of the cupboard.

Details of appropriate engineering firms, plastic fabricators etc can be obtained in each State from G.E.N.S.A. representatives.

It would be unfortunate if some States proceed with their proposed bans for endoscope reprocessing using glutaraldehyde, even in well contained systems. There is presently no alternative chemical disinfecting agent for manual reprocessing which is as effective and has a better safety profile. The many problems associated with automatic disinfectors are outlined in the appropriate section. In some units automatic disinfectors will prove to be a safe and effective means of reprocessing. Small units or occasional users may well find the expense and appropriate care and maintenance of the machines present major problems.

(d) Personal Protective Equipment

Only gloves that have been approved for use with glutaraldehyde should be worn. In view of the extensive range of gloves available on the market, it is suggested that the manufacturers be asked to provide information regarding the gloves suitability for use with glutaraldehyde.
Protective eye wear should be used. Full face shields proved the greatest protection against chemical and biological material splash.

Impervious aprons should also be used to prevent splashes coming in contact with clothing or exposed skin.

(e) Monitoring

The occupational health hazards of glutaraldehyde have been well documented and it is unacceptable that staff be expected to work in areas where adequate occupational health and safety measures have not been instituted\(^\text{257}\)\(^{273}\). Where staff develop symptoms or where there is any doubt as to the efficacy of control measures, Occupational Health and Safety personnel should be contacted.

B. Other Chemicals

There are unfortunately no chemical disinfectants suitable for endoscopes that are totally user friendly. It needs to be appreciated that while the Occupational Health and Safety problems of glutaraldehyde have been widely publicised, many of the newer compound agents appearing on the market have had little formal investigation of their irritant properties. Many of the chemicals used in closed systems can be highly dangerous if exposure occurs to a concentrated form. This includes peracetic acid and chlorine releasing agents. Storage of any large quantities of alcohol poses a significant fire hazard.

3. INFECTIOUS DISEASES

A. Infections, diseases transmitted by blood and other biological fluids

i. Human Immuno deficiency virus (HIV)

The greatest risk here is of needle stick injury. Staff with skin breaks (burns, cuts, fissures, cracking, dermatoses, etc) should have the appropriate area covered or be employed in areas where the possibility of blood or biological fluid contaminating the open area is negligible. The rate of sero conversion after exposure to HIV infected blood or other biological fluids ranges from 0.1% to 0.4%\(^\text{274-276}\). In general the greater the innoculum the greater the risk of disease transmission.

ii. Hepatitis B Virus (HBV)

Again the greatest risk is from needle stick injury. The sero prevalence of HBV is 2-4 fold higher in health care workers than in blood donors\(^\text{277,278}\). The risk of transmission by needle stick injury varies according to the e antigen status of the blood. Sero conversion occurs in 1-6% following e antigen negative blood exposure but rises to 20-40% with E antigen positive blood\(^\text{278,279-281}\).

iii. Hepatitis C Virus (HCV)

Again the greatest risk is from needle stick injury. The sero prevalence of Hepatitis C in health care workers does not appear to be increased over and above the general population\(^\text{282-284}\). It is estimated that sero conversion occurs following 1-10% of needle stick injuries\(^\text{284-286}\).

B. Management of Risk of Blood Borne Transmission

All endoscopy units should have an appropriate sharps disposal policy. Needle stick injury poses a very real threat of disease and careless practices by medical or nursing staff should not be tolerated.
All endoscopy units should have a clearly defined policy for needle stick and sharps injuries. In general this should follow the course laid out in A.N.C.A. Bulletin No.16, 1996 – Australian National Council on A.I.D.S, “Needle stick and blood accidents – management of exposure to blood/body fluids contaminated with blood including needle stick/sharps injuries with a potential for HIV or other blood borne infections”.

It is essential that swift action is taken to institute anti-retro viral therapy where appropriate\(^{287}\). This will include combined regimens for high risk exposure. It is again stressed that prophylaxis should commence **WITHIN HOURS** of high risk exposure\(^{287}\).

C. Infections, Diseases Transmitted by Aerosols

**Mycobacterium Tuberculosis**

See sections on *Mycobacterium tuberculosis* and Reprocessing of Bronchoscopes. It is again stressed that bronchoscopy should be avoided wherever possible in patients with known or suspected tuberculosis. There is a significant risk of nursing and medical staff contracting *Mycobacterium tuberculosis* when bronchoscopy is carried out on tubercular patients without proper precautions. Masks are particularly important where airborne infection may occur and a particulate mask capable of filtering 1 micron particle should be worn by endoscopy room staff during bronchoscopies and by patients during recovery phase if coughing.

D. Oral – Faecal Transmission Infection

Health care workers in endoscopy units frequently come into contact with patients with diarrhoeal diseases and Hepatitis, including Hepatitis A. Occupationally acquired disease amongst health care workers has been reported to include Salmonella, Hepatitis A, Shigella, Cryptosporidia, *Helicobacter pylori* and *E. coli*\(^{290}\). However, there are no reports that specifically document an increased risk to endoscopy unit staff. Hepatitis A vaccination may be appropriate for health care workers in endoscopy units.

4. OTHER HEALTH AND SAFETY ISSUES

A. Immunisation

All endoscopy personnel should be immunised against Hepatitis B and antibody titres checked on a regular basis.

The optimal management of needle stick injury with Hepatitis C positive blood is unknown but the administration of immuno globulin is not recommended.

B. Protective Clothing and Equipment

The possibility of splashing by blood and bodily fluids is not necessarily predictable and all personnel likely to encounter splashing (endoscopist and immediate assistant) should wear water repellent gowns which should be changed between cases if soiled.

C. Eye Protection

Endoscopists and their primary assistants should wear eye protection either face shields or glasses.

D. Gloves

Gloves should be worn wherever there is a risk of exposure to blood or body fluids. This will include all endoscopy personnel having direct procedural patient contact. Gloves used when reprocessing endoscopes must be impervious to glutaraldehyde and other chemicals. Sterile latex gloves are recommended for endoscopists and assistants during E.R.C.P.
E. Masks
Masks are particularly important where airborne infection may occur and a particulate mask capable of filtering one micron particles should be worn by endoscopy room staff during bronchoscopy. Masks should also be worn if there is a significant likelihood of splattering of blood or bodily substances. Special masks are required for use with high energy Yag lasers.

F. Latex Allergy
The conversion of natural rubber latex into commercial products is a highly complicated process involving the addition of a wide variety of chemicals. Leaching of natural and additional chemicals during the manufacturing process varies widely. Not all apparent “latex allergies” will in fact represent true reactions to latex but may be due to a wide variety of other chemicals remaining in the finished product. Systemic allergic reactions to latex are Type I immunological responses. Other reactions such as contact dermatitis may be due to Type IV delayed hypersensitivity reactions. Symptoms in Type I responses will include itching, rash, dermatitis, angio-oedema, urticaria, facial swelling, wheezing and rarely fainting or shock. Type IV reaction in the form of contact dermatitis is, however, the most common reaction.

The apparent dramatic increase in latex allergy in recent years appears to be due both to the increased use of latex containing products since the introduction of universal precautions and to differences in manufacturing techniques. Health care workers with a history of atopic disease (e.g. asthma, hay fever, eczema) are at increased risk of latex sensitisation. It is rarely necessary for health care workers in endoscopy units to use latex based gloves on a regular basis. Non-latex gloves including vinyl, polyethylene, plastic, neoprene or nitrile based gloves are suitable alternatives. Where latex containing gloves need to be worn fabric or other lining is usually available. Powder free gloves significantly reduce the amount of aerosolized latex particles, thought to be a major route of sensitisation.

Where latex allergy is suspected referral to a Specialist with experience in latex allergy testing is advised. It should be noted that some skin prick tests for latex allergy have been associated with severe reactions. Where latex allergy is suspected it is important to fully document the clinical situation. Where contact reaction is established then strict avoidance of further latex exposure is important to prevent the development of systemic manifestations. Where systemic manifestations have developed, total occupational avoidance is critical and sufferers need to be warned of the risks of latex exposure during medical or surgical procedures.

It is important to take patients’ statements that they are allergic to latex seriously. Severe latex allergy reactions have occurred after simple rectal examinations done using latex gloves. Apparently one incident has included cardiac arrest. It is therefore important that staff do not use latex gloves in the examination of patients with known or suspected latex allergy.

Consideration should also be given to appropriate selection of equipment when performing oesophageal and haemorrhoid banding procedures. Latex free bands are available.
References


75.


225. Reuse of single-use medical devices: NHMRC deliberations. MJA 1996;164,537.


76.


Guideline Application Statement

These guidelines have been prepared by the Gastroenterological Nurses Society of Australia and the Section of Endoscopy of the Gastroenterological Society of Australia and every care has been taken in their compilation. The guidelines are intended to be used as a guide only and not as an authoritative statement of every conceivable step or circumstance which may or could relate to the performance of the procedures outlined. Practitioners should use these guidelines as an aid in relation to disinfection and not as a complete or authoritative statement of such procedures.

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