NATIONAL COORDINATING COMMITTEE ON THERAPEUTIC GOODS
AUSTRALIA

REDUCING PUBLIC HEALTH RISKS ASSOCIATED WITH REUSABLE MEDICAL DEVICES

May 2004

This document is issued on behalf of the National Coordinating Committee on Therapeutic Goods (NCCTG) to provide information and recommendations to reduce the potential public health risks associated with reusable medical devices.

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Foreword

The National Coordinating Committee on Therapeutic Goods (NCCTG) Expert Working Group on Reusable Medical Devices (Expert Working Group) has produced this document to assist health care facilities and health care professionals reduce the potential public health risks associated with reusable medical devices, particularly those instruments that are difficult to clean, disinfect and sterilize.

The document discusses issues (other than those covered by the relevant Standards) that affect the ability to clean and sterilize reusable medical devices and is intended to complement:

- AS/NZS 4187:2003 *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment and maintenance of associated environments in health care facilities, or* AS/NZS 4815:2001**:** for Office-based health care facilities*;*
- *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting – January 2004,* and
- Other relevant Standards, guidelines and policy documents published by health care professional organisations and health authorities.

The NCCTG is a sub committee of the Australian Health Ministers' Advisory Council (AHMAC). Its functions are to take action necessary to bring about coordination of legislative and administrative controls on therapeutic goods and poisons and to make recommendations to the Australian Health Ministers' Advisory Council as necessary. The committee is serviced by the Therapeutic Goods Administration (TGA), a Division of the Department of Health and Ageing.

The TGA is responsible for administering the Therapeutic Goods ACT 1989 to ensure the quality, safety, efficacy (for higher risk therapeutic goods) and timely availability for therapeutic goods supplied in Australia. Under this legislation, medical devices must, prior to supply in Australia:

- Be entered on to the Australian Register of Therapeutic Goods;
- Be manufactured under a quality system appropriate for the class of device; and
- Meet the Essential Principles relating to the safety and performance set out in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 [(44)].

As part of its regulatory responsibilities the TGA also operates a number of post market vigilance programs, one of which is the Incident Reporting and Investigation Scheme (IRIS) which investigates reports of incidents relating to medical devices.

The membership of the NCCTG Expert Working Group

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The Terms of Reference

- To examine the design and use of reusable devices that cannot be dismantled or are difficult to clean and sterilize or disinfect which may potentially pose a risk for public health;
- To develop criteria for the investigation of patient exposure in the event of a report of possible breaches of infection control for these types of device;
- To propose any necessary action in response to the potential public health risks and product design issues; and
- To consider establishing a model protocol that can be used in response to future incidents by State and Territory health authorities.

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Executive summary

In 2003, an expert working group was convened under the auspices of the National Coordinating Committee on Therapeutic Goods (NCCTG) to examine the public health issues associated with reusable medical devices that are difficult to clean, disinfect and sterilize. This was in response to two recalls of two different ranges of orthopaedic instruments that were found to contain residual biological materials that had not been removed by normal cleaning and reprocessing procedures.

The Expert Working Group produced this document to assist health care facilities and health care professionals reduce the public health risks associated with reusable medical devices, particularly semi-critical and critical instruments. The document discusses the potential risks, the major factors that contribute to creating difficulties for cleaning and reprocessing and makes some recommendations for reducing the associated public health risks.

A. Literature review

The Expert Working Group's review of the literature suggested that infectious disease outbreaks linked to contaminated medical devices exists but is scant. The use of prophylactic antibiotics, the nature of the infectious agents, the low rate of incident reporting and the lack of consideration of the instruments in investigations into post-operative surgical site infections (or health care acquired infections) are likely to result in an underestimation of the true extent of the problem. However, there are clear examples of patient to patient transmission of serious infectious diseases such as tuberculosis, hepatitis B and C, and Creutzfeldt-Jakob Disease following cleaning, disinfection and sterilization failures.

B. Key factors that affect public health risks

The Expert Working Group concluded that factors critical to reducing public health risks associated with reusable medical devices are:

- Instrument/ device design;
- The policies and practices of health care facilities and health care professionals;
- The availability of manufacturer's instructions for cleaning, disinfection or sterilization for instruments /devices;
- Purchasing decisions; and
- Effective incident reporting and investigation programs.

Consequently all the major stakeholders (manufacturers, suppliers, purchasing committees, health care facilities, health care professionals, health authorities and the national regulator) have a shared responsibility in reducing the risks associated with reusable medical devices.

B1. Instrument design and types of devices that pose difficulties for cleaning

Design configurations such as matted surfaces, sharp angles, occluded dead-ends, rough or pitted surfaces, square corners, dead spaces, rough edges and complex jaw assemblies are likely to trap bioburden and debris [31] and complicate the cleaning process. Devices with lumens, long narrow shafts, articulations, furrows and irregular surfaces also present challenges for cleaning, disinfection and sterilization as it is impossible to access or visualise the entire surface that needs cleaning [32,33].

Loan sets, privately owned devices and instrument containers were also identified by the Expert Working Group as posing potential public health risks. These instruments are often inadequately cleaned prior to leaving a facility, may be damaged in transit and are delivered to

the next health care facility with minimal time for reprocessing before use in a scheduled procedure.

Instrument containers are often manufactured from materials that do not support the weight of the instruments or cannot withstand the heat generated during sterilization processes. As a result these containers may break resulting in potential contamination of the sterile packaging. Fragments of the broken container may potentially contaminate a sterile surgical field.

Medical devices, particularly instruments, are often replaced only when they are beyond repair. Consequently, older, superseded medical devices may remain in circulation long after new, redesigned instruments have been purchased. Decommissioning superseded medical devices that are difficult to clean could assist in reducing the public health risks associated with these types of medical devices.

Recommendations

- Reusable medical devices need to be designed to enable adequate reprocessing.
- Instrument containers need to be designed from robust materials to withstand sterilization and to protect instruments in transit and storage.
- Health care facilities and instrument providers need to collectively develop standardised procedures for managing loan sets and privately owned instruments including allowing sufficient time for cleaning and sterilisation.
- Health care facilities need to consider implementing programs to review and decommission superseded medical devices.

B2. Policies and work practices of health care professionals and health care facilities

Theatre Sterilization Services Units (TSSUs) and Central Sterilizing Supply Departments (CSSDs) make a significant contribution to the quality of patient services provided by health care facilities. Some TSSUs/CSSDs also assume responsibility for peripheral sterilizing facilities[39]. Consequently, the activities of the TSSU or CSSD need to be integrated into the Total Quality Management System for the health care facility.

Adequate infection control in CSSD depends upon factors such as adequate numbers of suitably qualified staff [38,39], education and ongoing training of CSSD staff and adherence to local and State infection control guidelines and the relevant Australian/New Zealand Standards for cleaning, disinfecting and sterilizing reusable medical devices.

The manner in which health care professionals care for the instruments can affect the ability of the instruments to be cleaned. Keeping instruments free from gross soiling and minimising the time between instruments leaving the operating rooms and arriving in the cleaning areas will reduce the risk of biological material drying on the instrument and becoming lodged in grooves and crevices[31].

The time required to reprocess frequently used medical devices should be taken into consideration to ensure adequate quantities are purchased to meet operative demands. When scheduling procedures, it is important to ensure the CSSD/TSSU has sufficient time allocated to reprocess the medical devices between procedures.

Recommendations

- Health care facilities should:
  - recognise the important role CSSDs and TSSUs play in infection control;
  - recognise the importance of developing skilled technicians in TSSU and CSSD;
  - implement education and training programs for TSSU and CSSD staff;
- Health care professionals should:
  - ensure instructions for use provided with the packaging, is not discarded at the point of use and reaches the CSSD or TSSU;
  - implement quality protocols for handling and reprocessing instruments;
  - keep devices free from gross soiling by rinsing or wiping soil off at the point of use;
  - minimise time between the devices leaving the clinical rooms and reaching the cleaning area; and
  - consider reprocessing times of frequently used devices when scheduling procedures.
- Perioperative, CSSD and TSSU personnel who reprocess reusable instruments should:
  - incorporate the manufacturer's instructions for reprocessing into Quality Improvement/ Risk Management Plans;
  - follow the manufacturer's instructions for reprocessing;
  - adhere to the relevant Australian/ New Zealand Standard for cleaning, disinfecting and sterilizing instruments – either AS/NZS 4187:2003 for hospitals or AS/NZS 4815:2001 for office based health care facilities; and
  - comply with local and State infection control guidelines.

B3. Manufacturer's instructions for use

The manufacturer's instructions for use provide valuable information about cleaning, disinfection and sterilization procedures for the perioperative, TSSU and CSSD staff. If adequate instructions are not available these personnel may be forced to adopt a "trial and error" approach to the reprocessing of a medical device. This "trial and error" approach could result in personnel disassembling a device that is not designed to be disassembled, or failing to disassemble a device when such measures are required to facilitate adequate cleaning. Furthermore, inappropriate or ineffective disinfection or sterilization processes may be used.

Recommendations

- Manufacturers should:
  - consider, as part of the design, the ability to disassemble and reprocess the device;
  - provide accessory aids to facilitate cleaning, particularly fordevices with complex designs;
  - ensue the instructions for use are appropriate for Australia context and accompany all devices supplied in Australia.
- Suppliers/manufacturers, health care facilities and health care professionals should ensure personnel handling medical devices receive adequate education and training on the care and handling of these devices, especially those incorporating new technologies.
- Health care professionals using the device should ensure instructions for use provided with the packaging, is not discarded at the point of use and reaches the CSSD or TSSU;
- CSSD and TSSU personnel should incorporate the manufacturers instructions in the Quality System Controlled Document process for maintenance as a quality record; and
- Perioperative, CSSD and TSSU personnel should report cases of inadequate or inappropriate instructions for use to the manufacturer or supplier as well as the TGA (through the Incident Reporting and Investigation Scheme (IRIS)).

B4. Purchasing decisions

Purchasing departments or committees can directly influence the health risks associated with reusable medical devices by ensuring devices with appropriate design characteristics and reprocessing instructions are purchased and used within their facility. Information critical to making informed purchasing decisions may be obtained through consultation with the instrument supplier, the users of the device, the perioperative and CSSD staff, and Infection Control staff. Key issues for consideration include the facility's ability to reprocess the device, in terms of both staff skills and existing equipment, and the need for training in the use and reprocessing of new devices.

Recommendations

- When considering the purchase of new devices, purchasing committees should:
  - consult with the users of the instruments, the perioperative and CSSD staff, biomedical engineering and Infection Control staff to assess their needs and issues;
  - consider the design characteristics and the adequacy of manufacturer's reprocessing instructions when assessing a device's ability to be cleaned;
  - ensure the device is compatible with existing reprocessing equipment;
  - check the reprocessing time and purchase sufficient units to ensure the medical device can be reprocessed within realistic timeframes to meet demands;
  - ensure facility staff are qualified or will receive training in the reprocessing of the particular device; and
  - consider developing checklists to guide their purchasing decisions.

C. Incident reporting and investigation

Medical devices that cannot be cleaned readily should be reported to the supplier or manufacturer and through the Incident Reporting and Investigation Scheme (IRIS) to the TGA.

A breach of infection control may be the first time the ability to clean, disinfect or sterilize a device properly may be questioned. Under these circumstances it is important that health care facilities have effective systems for investigating the infection control breach and for informing health authorities and the product regulator (the TGA).

An effective reporting system accurately determines which events should be reported and to whom. It provides a mechanism to make, act on, and track reports, and to track any corrective actions. The reporting of events, the outcomes of investigations and the remedies implemented by an institution to health authorities allows potential systemic problems to be identified. Preventive measures can be instituted more broadly across a range of health care facilities, which can ultimately benefit the entire health care community.

D. Product identification and traceability (refer AS/NZS 4187-2003, S. 8.5.2 and page 19)
"Procedures should be in place to link steriliser cycle batch information to items that have been sterilised, to the patient to:

- facilitate the recall of products in the event of sterilising equipment failure;
- facilitate compliance with Australian Standard 4187 that mandates a product recall mechanism; and
- minimise the risk of litigation arising from the use of unsterile instruments (AS/NZS 4187-2003, p. 63).

Recommendations

- Medical devices that due to their design cannot be cleaned adequately should be reported to the supplier/manufacturer and the Incident Reporting and Investigation Scheme (IRIS) at the TGA;
- Health care facilities and health authorities should consider implementing an incident investigation and reporting program for reusable medical devices that includes:
  - regular routine reporting to health authorities;
  - reporting incidents relating to instrument design to the TGA and the supplier;
  - communicating outcomes of investigations;
  - implementing corrective action; and
  - monitoring the effectiveness of the incident reporting program

Part A: Literature Review – Incidence of Infection Linked to Contaminated Medical devices

1. Introduction

Medical devices must be adequately decontaminated prior to reuse or they may be a source of health care acquired infection.

Evidence of infectious disease outbreaks linked to contaminated medical devices exists but is scant. Many decisions regarding the adequacy of cleaning and reprocessing will need to be made on the basis of two criteria - the use to which the medical device is being put, and the susceptibility of various infectious agents to the processes.

Medical devices can be classified according to use - items that will enter a sterile body site (critical), items that make contact with mucous membranes or non-intact skin (semi-critical) and items that make contact with intact skin only (non-critical)[(1)]. This classification system (the Spaulding classification system) determines the level of reprocessing required. Critical items require sterilization (the complete elimination of all forms of microorganisms including bacterial spores). Semi-critical items require high-level disinfection (the elimination of all microorganisms with the exception of high numbers of bacterial spores). Non-critical items require thorough cleaning with detergent and water but no further reprocessing [(2)].

Infectious agents vary with regard to their susceptibility to reprocessing for reuse. Vegetative bacteria and enveloped viruses are usually the most sensitive to chemical disinfectants and bacterial spores and protozoan cysts are the most resistant[(3)]. A similar gradient exists with respect to susceptibility to steam sterilization. The prion causing Creutzfeldt-Jakob Disease (CJD) is more resistant to sterilization processes than any other known infectious agent and hence requires unique reprocessing procedures[(4)].

2. Sterilization

Sterilization may be achieved using thermal or chemical methods. For reasons of speed, efficiency, safety and cost, steam sterilization is the preferred method for all but heat sensitive items. Heat sensitive items can be sterilized using gas (ethylene oxide or hydrogen peroxide) or liquid (peracetic acid) or gas/liquid combination systems. All sterilizing, regardless of the method used, must be preceded by thorough cleaning (mechanical methods are preferable to manual cleaning, refer AS/NZS 4187-2003) in order to decrease the microbial load and remove organic material that can interfere with the sterilization process. It is generally accepted that this is particularly important in low-temperature sterilization systems where it is critical that the sterilant makes contact with the entire surface of the item being sterilized in order to be effective.

3. High Level Disinfection

High level disinfection may be achieved in general by one of two methods:

- Disinfection in a batch washer at specific temperatures as per AS/NZS 4187-2003; or
- Soaking a cleaned item in a chemical solution.

Batch washer disinfection is usually used for the processing of heat sensitive anaesthetic and respiratory items.

In relation to gastrointestinal endoscopes and bronchoscopes, high level disinfection may be achieved using a number of products registered as instrument grade disinfectants in Australia. For example, the reprocessing of heat-sensitive endoscopes requires the following steps:

- Mechanical or manual cleaning of all external surfaces, ports and internal channels with water and a detergent or enzymatic cleaner;
- Full immersion of the item in high level disinfectant ensuring that all external and internal surfaces make contact with the solution;
- Rinsing using sterile water, 0.22+ 0.01um filter water or tap water (instruments intended for sterile sites must be rinsed with sterile water, refer AS/NZS 4187, Section C.2.6.3);
- An ethanol (alcohol) rinse (used only to assist forced air drying of channels); and
- Drying (using forced air to dry all channels) and storage disassembled in a way that prevents re-contamination[5].

A number of factors affect the efficacy of high level disinfection including:

- The microbial load;
- The presence of organic matter; and
- The concentration, temperature and duration of exposure to the high level disinfectant.

These factors all highlight the need for meticulous adherence to reprocessing protocols if cross-infection via semicritical instruments is to be avoided.

4. The Creutzfeldt-Jakob Disease (CJD)

The only infectious agent that requires unique reprocessing methods is the prion that appears to cause CJD[49]. Inactivation of the CJD infectious agent requires exposure to steam under pressure for longer periods or exposure to higher concentrations of disinfectants than is required for any other known infectious agent. When determining the appropriate methods for reprocessing, the Communicable Diseases Network Australia (CDNA) recommends classifying an instrument according to the Spaulding criteria, the demonstrated or predicted infectivity of human tissue with which the instrument has had contact and the contribution of cleaning to the reprocessing procedure[6]. Instruments or devices that will have contact with high infectivity sites (eg brain, pituitary gland, spinal cord and the retina or optic nerve of the eye) must be decontaminated using more stringent methods or discarded depending on the patient risk category. For example contaminated medical devices that have had contact with high infectivity tissues in high-risk patients must be discarded. Critical and semi-critical items having contact with medium or low risk tissues in lower risk patients may be decontaminated using conventional methods[6].

5. Infectious disease outbreaks associated with failures of reprocessing of instruments

5.1 Instruments subject to steam sterilization

With the exception of patient-to-patient transmission of CJD via contaminated neurosurgical instruments, very few infectious disease outbreaks linked to items sterilized using steam have been reported. Some examples are shown in the following table. In the case of CJD transmission, the incidents were believed to have occurred because inactivation of the CJD prion requires exposure to steam under pressure for a longer period than is required to inactivate conventional pathogens.

Table 1: Examples of Instruments Subject To Failure of Steam Sterilization

Instrument /Device	Infectious Agent	Reprocessing Failure	Solution/ Proposed Solution
Neurosurgical Instruments	Creutzfeldt-Jakob Disease [8]	Agent resistant to conventional steam sterilization parameters	Modify reprocessing of equipment according to CJD risk status of patient and CJD risk status of tissue being contacted
Intravenous fluids	Enterobacter [9,10]	Design of screw caps on bottles prevented contact of organism with steam during sterilization cycle	Redesign of IV fluid bottles

5.2 Instruments subject to low temperature sterilization or high level disinfection

From the references cited, the majority of infectious disease outbreaks appear to be linked to medical devices that had undergone failures of low temperature sterilization or high level disinfection such as gastrointestinal endoscopes or bronchoscopes. Outbreaks of blood borne viruses, mycobacteria and enteric organisms have been reported. Most failures resulted from a breakdown in one or more of the reprocessing steps. In particular, failure to completely clean small ports, channels and biopsy forceps, failure to soak the instrument properly so that all surfaces are contacted by the disinfection solution and contamination of automatic washer disinfectors with waterborne organisms (see table below). In addition, patient-to-patient transmission of CJD via contaminated electroencephalogram (EEG) electrodes has been reported. The transmission of CJD was believed to have occurred because the CJD agent is resistant to formaldehyde at the concentrations used.

Table 2: Examples of Instruments Subject To Failure of Low Temperature Sterilization/ High Level Disinfection

Instrument/ Device	Infectious Agent	Reprocessing Failure	Solution/ Proposed Solution
Gastrointestinal Endoscopes	HBV [11]	Non-immersible endoscope. Air-water channel not exposed to disinfecting solution	Endoscope design altered – fully immersible
	HCV [12]	Failure of cleaning and soaking of endoscope and failure to steam sterilize biopsy forceps	Adherence to national reprocessing guidelines
	Salmonella spp. [13,14]	Inadequate manual cleaning, disinfection or storage techniques	As above
	E.coli [15]	As above	As above
	Enterobacter spp. [16]	As above	As above
	Helicobacter pylori[14]	As above	As above
	Klebsiella [15]	As above	As above
	Serratia marcescens[17]	As above	As above
	Strongyloides [18]	As above	As above
	Pseudomonas[19, 20,21,,22]	Contamination of instrument via the rinse water	As above
Bronchoscopes	Multi-drug resistant TB[23]	Inadequate cleaning and disinfection of bronchoscope	Adherence to current national reprocessing guidelines
	TB[24]	As above	As above
	Atypical	As above	As above

	mycobacteria[25]		
	Pseudomonas[26]	As above	As above
Steroetactic EEG electrodes	CJD[27]	Agent resistant to formaldehyde	Modify reprocessing of equipment according to CJD risk status of patient and CJD risk status of tissue being contacted

5.3 Instruments subject to cleaning

Patient-to-patient transmission of infection has also been linked to medical devices that are multi-patient use but are difficult to clean. Examples include the transmission of hepatitis C virus (HCV) in contaminated anaesthetic circuitry and the transmission of multi-drug resistant *Mycobacterium tuberculosis* via nasal atomisers. The prevention of further outbreaks has involved recommendations to make the devices single use or to use viral and bacterial filters in the case of anaesthetic circuits.

Table 3: Examples of Instruments Subject To Failure of Cleaning

Instrument/ Device	Infectious Agent	Reprocessing Failure	Solution/Proposed Solution
Nasal atomisers	TB [28]	Atomiser not cleaned between patients	Single-use
Anaesthetic circuits	HCV [29,30]	Antiviral filters not used on anaesthetic circuit	Use of anti-bacterial and anti-viral filters on anaesthetic circuitry

6. Comments

There are far fewer infectious disease outbreaks linked to medical devices that have been steam sterilized. This may be because instruments that are steam sterilized are generally simpler in design and more readily cleaned than heat sensitive instruments. It has also been suggested the process of steam sterilization is likely to be effective even in the presence of small residual quantities of organic matter[2,7].

Non-critical medical devices (ie. those that require only thorough cleaning for reprocessing) can still be a source of patient-to-patient transmission of infection if they cannot be cleaned adequately.

Published reports of cross-infection secondary to inadequately reprocessed medical devices may represent a significant underestimation of the true extent of this problem because:

- Prophylactic antibiotics may mask surgical site infections;
- Investigations of surgical site infections or healthcare associated infections rarely include consideration of the instruments used during the procedure; and
- The nature of the infectious agents likely to be transmitted, infectious agents:
  - May have a long incubation period (eg. blood borne viruses, *Helicobacter pylori*, CJD),
  - May not be subject to routine screening (eg. blood borne viruses, enteric flora),
  - Do not require notification to a public health authority and hence escape recognition as an outbreak (eg. enteric flora), or
  - May be incorrectly attributed to another source (eg. blood borne viruses).

7. Summary

- Failure to adequately reprocess reusable medical devices is an important source of cross-infection within health care facilities and has the potential to be minimised;
- If a medical device cannot be cleaned adequately, it should not be regarded as being able to be reprocessed safely, irrespective of the reprocessing method used;
- Beyond initial cleaning, adequate reprocessing will be achieved through adherence to current, national reprocessing guidelines; and
- Reprocessing of medical devices used in patients at risk of having CJD requires special consideration.

Part B: Factors That Affect Public Health Risks

B1. Instrument Design.

1. Introduction

Instrument design is a major contributing factor to the ability for some reusable medical devices to be cleaned, disinfected and sterilized for reuse. Manufacturers have made much progress in producing new and improved technologies but the primary focus has been on the functionality of the medical devices during the procedure[31]. It is only in recent times that manufacturers have begun to pay more attention to designing medical devices that are not only functional but are able to be cleaned, disinfected and sterilized adequately.

2. Design features that create difficulties for cleaning

Despite the best efforts of Theatre Sterilization Units (TSSUs) or Central Sterilizing Supply Departments (CSSDs) to follow cleaning, disinfection and sterilization protocols, instrument design causes debris to remain on some medical devices and possibly or potentially contributes to post-operative morbidity[32].

The following examples of design features, that create difficulties for cleaning and sterilization were compiled from the literature and expert advice from perioperative nurses, CSSD and TSSU personnel and are indicative only.

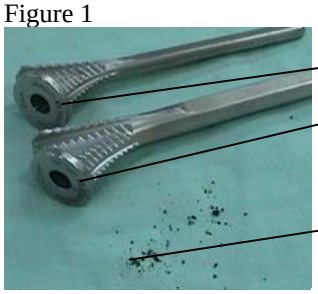
Table 4 Examples of design features that create difficulty for cleaning

Acute and sharp angles	Grooves and serrations	Occluded dead ends
Articulations	Hinges	Seals
Complicated box hinges	Hollow lumens and tubing	Springs
Devices that cannot be locked open	Joints and joins	Taps
Dead spaces	Long narrow shafts	Teeth and jaws
Flexible coils	Lubricated instruments	Valves
Furrows	Multi-component devices	

Design configurations such as matted surfaces, sharp angles, occluded dead-ends, rough or pitted surfaces, square corners, dead spaces, rough edges and complex jaw assemblies are likely to trap bioburden and debris [31] and complicate the cleaning process. Medical devices with lumens, long narrow shafts, articulations, furrows and irregular surfaces also present challenges for cleaning, disinfection and sterilization as it is impossible to access or visualise the entire surface that needs cleaning [32,33].

Single component instruments that, on visual examination, appear to be clean may harbour debris as a result of their design[32]. Figure 1 shows debris found in the crevices of an orthopaedic instrument that was only detectable with the assistance of a light source.

Figure 1



Photograph courtesy of Totalcare Sterilizing Services

Laparoscopic instruments have been found to harbour debris at junctions between insulating sheaths[33]. The presence of debris on these types of instruments can be attributed to their complexity in design, the presence of furrows and grooves, channels that cannot be visualised and routinely checked[33] and the small size of the functional components. Studies found that the irregular surfaces of laryngeal blades and handles are frequently contaminated with visible and hidden blood [34] and that residual patient debris can remain on reusable endoscopic forceps despite vigorous cleaning [35, 36].

3. Instruments most commonly identified as difficult to clean

Perioperative nursing, CSSD and TSSU personnel have identified the following examples of medical devices .

Table 5 Examples of medical devices that have been difficult to clean

General instruments		
Anaesthetic bougies	Insulated or electrical devices	Skin mesher
Electro surgical devices	Laryngeal masks	Stress incontinence devices
Filshie clip applicators	Leach Wilkinson cannula	Tonsil snares
Foetal monitoring tips	Otis urethrotome	Valtchev manipulator
Laparoscopy endoscopy instruments		
Bronchoscopes	Endoscopic biopsy forceps	Hot biopsy forceps
Cholangiogram forceps	Endoscopic snares	Hysteroscopy biopsy forceps
Colonoscope biopsy forceps	Flexible grasper	Laparoscopic forceps
Diathermy tips and loops	Gastroscope biopsy forceps	Laparoscopic sheaths
Endoscopes flexible and rigid	Grasping forceps	
Motorised instruments		
Air powered devices	Drills and Drill reamer gun	Neuro perforator
Cement gun	Micro drills	Phaco hand pieces
Craniotome	Midas Rex drill	Saws
Needles and cannulas		
Gift probe	Liposuction cannulae	Spackman cannula
Leach Wilkinson cannula	Pudendal nerve block needles	Verres needles
Ophthalmic instruments		
Aspirator needles	Fine retinal instruments	Phaco needles and tubing
Orthopaedic instruments		
Acetabular reamer head handles	Hip broaches	Orthopaedic loan trays
Bone rasps	Hudson brace	Nail reamers
Cement bowls	Laminectomy rongeurs	Rongeurs
Endo fibres (dental)	Matrix bands (dental)	Slap hammer adaptors
Flexible reamers	Orthopaedic impactors	Small fragment set
Guide pins		
Suction and related equipment		
Ear nose and throat (ENT) suckers	Stapedectomy suckers	Verhoven suckers
Micro suckers	Suction tubing	Yanker suckers
Poole suckers	Thames instrumentation	Zolner suckers
Smiths sucker	Urology uro-mat	

4. Loan sets and privately owned medical devices

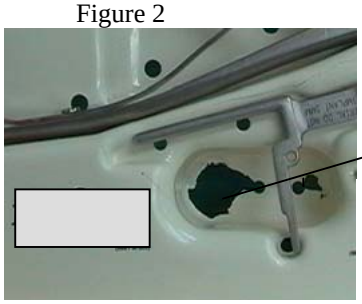
Loan sets and privately owned medical devices delivered to health care facilities for use during specific procedures pose specific challenges. According to experts in CSSD and perioperative nursing, these medical devices are often:

- Inadequately cleaned prior to leaving the previous facility or may be damaged in transit;
- Not accompanied by information about the degree/standard to which they have been processed in the previous user facility;
- Delivered to the health care facility just prior to a scheduled procedure commencing and thus require processing for use within a relatively short time frame;
- Specialised devices that the TSSU or CSSD staff may not be familiar with; and
- Not accompanied by instructions for cleaning, disinfection and sterilization.

5. Instrument containers

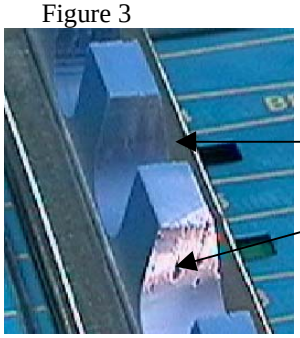
Instrument containers may also pose potential public health risks. These containers are often manufactured from materials that do not support the weight of the instruments and/or cannot withstand the heat generated during the sterilization process. As a result the containers may break during transit or storage resulting in potential contamination of the sterile packaging. The containers may deteriorate or degrade during the sterilization process resulting in foreign matter adhering to or damaging the instruments. Figure 2 shows large holes in an instrument container. The broken pieces from the container were found in the sterile drapes. Figure 3 is a photograph showing damage caused to the instrument container by the instruments. This damaged surface of the instrument container could result in the surface coating of the container falling into the drapes and become a contaminant.

Figure 2



Photograph courtesy of Totalcare Sterilizing Services 26 May 2003

Figure 3



Photograph courtesy of Totalcare Sterilizing Services 4 August 2003

6. Superseded instruments that are difficult to clean

Developing and implementing programs to review and decommission superseded medical devices that are difficult to clean could reduce the potential public health risks associated with reusable medical devices.

Generally speaking, medical devices are often replaced only when they are beyond repair, long after redesigned and more readily cleaned models are available for purchase.

A policy of only replacing instruments when they are beyond repair is also likely to result in a mismatch and potential incompatibility of instruments within instrument trays.

7. Reporting incidents associated with instrument design

In situations where, due to design, an instrument is difficult to clean or has not been decontaminated properly, health care professionals (including CSSD and TSSU personnel) should report the incident directly to the supplier or manufacturer and to the TGA through the IRIS program.

If the design of an instrument prevents it from being cleaned and reprocessed properly, the TGA is able to liaise with the supplier, the manufacturer and overseas regulatory agencies to attempt to have the problem remedied.

Information on the IRIS and an Incident Report Form is at Attachment A.

8. Redesign not the only solution

The Expert Working Group acknowledged that, due to time and commercial considerations, redesigning a medical device may not always be the most practical, efficient or cost effective solution.

Once a decision is made to redesign or create a new instrument, it may take up to six years to bring the finished instrument to market. The design must be drawn, brought to scale and scrutinised. Prototypes need to be made, tested and evaluated, taking approximately six to twelve months. It may then take up to two years for a patent before production planning can begin and applications are submitted for regulatory approval[(37)].

The Expert Working Group acknowledged there are other efficient, equally effective and less costly measures that can reduce infection risks associated with reusable medical devices. These measures involve the work practices and policies of stakeholders, including health care facility administrators, health care professionals and health authorities.

B2. Policies and work practices

1. Introduction

The policies of health care facilities and work practices of health care professionals (including perioperative, CSSD and TSSU personnel) can also impact on the public health risks by influencing the ability to clean and decontaminate medical devices for reuse.

2. Policies of health care facilities

TSSUs and CSSDs make a significant contribution to the quality of services provided by health care facilities. Some TSSUs/CSSDs also assume responsibility for peripheral sterilizing facilities[38]. Consequently the activities of the TSSU or CSSD need to be integrated into the Total Quality Management System for the health care facility.

The general trend in Australia has been to include sterilizing services CSSDs as part of other hospital services such as linen supply services or domestic catering services rather than as a specialised medical support service. This can undermine the important role of the TSSU/CSSD in patient safety and infection control[39].

There is also a tendency, for economic reasons, for health care facilities to employ unskilled personnel within a CSSD or TSSU to process reusable medical devices including semi critical and critical instruments. Unskilled CSSD and TSSU personnel are unlikely to have expertise in or knowledge of:

- The principles of infection control;
- The importance of thorough cleaning prior to disinfection and sterilization;
- The reasons for adherence to stringent procedures; or
- The consequences of taking "short cuts".

Also, when placed under pressure to meet demands, personnel may feel compelled to circumvent procedures in order to deliver the item in time for scheduled procedures.

Effective infection control procedures in the CSSD depends upon:

- Adequate numbers of suitably trained and qualified staff [38,39];
- Effective communication between departments, the administration and the CSSD;
- Appropriate education and ongoing training of CSSD staff employed to process reusable medical devices used by the facility; and
- The technical, business and human resource management skills of CSSD managers.

Reprocessing reusable medical devices, particularly semi-critical and critical instruments, needs to be recognised as a speciality requiring skilled personnel. Furthermore, to ensure high quality infection control, work practices in the TSSU/CSSD, should be based, where possible, on:

- The Australian/New Zealand Standard *AS/NZS 4187:2003 Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment and maintenance of associated environments in health care facilities*;
- Infection control guidelines published by health authorities;
- Standards and Guidelines published by health care professional organisations such as the Australian College of Operating Room Nurses (ACORN) Standards- *Reprocessing Reusable Items: Cleaning Packaging, Sterilization and Storage of Sterile Supply*; and
- The manufacturer's instructions for use.

CSSD and TSSU managers can reduce or eliminate the pressures placed upon staff to circumvent standard operating procedures by advising purchasing departments of the timeframes needed to reprocess the devices and quantities that need to be purchased to meet demands. Managers should also insist on receiving and reviewing the manufacturer's instructions for use, prior to undertaking any reprocessing. This action will ensure the devices are reprocessed according to tested and validated reprocessing procedures and assist the CSSD or TSSU to identify those devices that are reusable and those intended for single use.

3. Health care professionals

Health care professionals can have a significant impact on the prevention health care acquired infections[31] or transmission of infection from contaminated instruments. The manner in which medical devices are cared for during and following use can affect the ability for the instruments to be cleaned. Keeping instruments free from gross soiling and minimising the time between instruments leaving the operating rooms and cleaning will reduce the risk of biological material drying on the instrument and becoming lodged in grooves and crevices[31].

Recognition that the reprocessing of complex and difficult to clean medical devices is time consuming and factoring this time into the scheduling of procedures will have a positive effect on the quality outcomes of the cleaning, disinfection and sterilization process[31] as it will eliminate the need for CSSD and the TSSU and operating room personnel to compromise Standard Operating Procedures in order to deliver the reprocessed devices in time for scheduled procedures.

4. Tracking individual instruments

- Useful solution but very resource intensive and only as good as the level of compliance that is achieved in the facility.
- Tracking every instrument to each patient on whom it is used is the ultimate level. It is only achievable via electronic means.
- Whether its higher cost is justifiable in public health terms is a moot point.
- Can have advantages in careful and rigorous management of instrument inventory.
- Value/necessity for tracking certain maintenance-demanding instruments.

B3. Manufacturer's Instructions

1. Introduction

From October 2002, all medical devices included on the Australian Register of Therapeutic Goods (ARTG) must to meet the Essential Principles for safety and performance[40,]. Devices entered into the ARTG prior to October 2002, have a five-year transition period and must so meet the Essential Principles by October 2007.

These Essential Principles include the requirement for the manufacturer's instructions for use to be provided with the medical device unless the medical device is low risk and can be safely used for its intended purpose without instructions. If the medical device is intended by the manufacturer to be disinfected or sterilized before use, the instructions for use should include information about the recommended cleaning, disinfection and sterilization procedures [40,] which, if followed, will ensure the medical device continues to comply with the Essential Principles. Furthermore, the instructions for use should also include the number of times the device may be safely reused[40,41].

2. The importance of the instructions for use

In the absence of cleaning instructions CSSD and TSSU personnel may need to devise their own "trial and error" approach for reprocessing. This can lead to disassembly of instruments not designed to be disassembled, failure to disassemble devices to facilitate adequate cleaning and/or use of inappropriate or ineffective reprocessing methods.

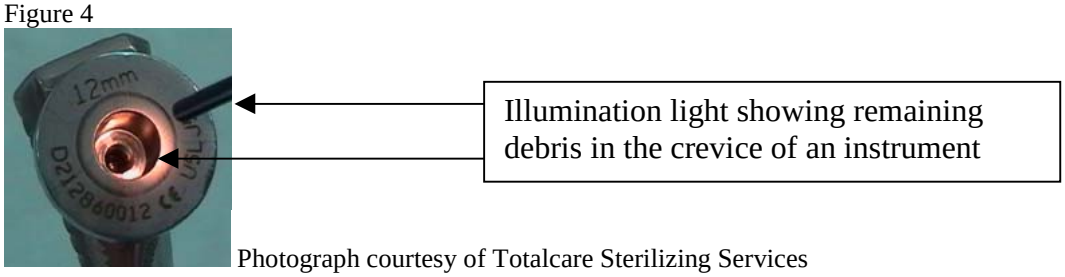
This may result in breaches of infection control and adversely affect device performance resulting in further risk to patient outcomes. In addition, the manufacturer's warranty may be voided in situations where the instructions for use are not followed.

3. Suggested actions

Manufacturers and suppliers can have a positive effect on reprocessing medical devices by:

- Considering cleaning issues when designing instruments;
- Providing comprehensive instructions for reprocessing the instruments,
- Providing education and training on the care and handling of the instruments; and
- Providing accessory aids such as specialised cleaning brushes and light sources (Figure 4) to assist with visualisation of crevices, deep holes etc.

Figure 4



Photograph courtesy of Totalcare Sterilizing Services

Operating room and CSSD managers can also improve infection control procedures by:

- Ensuring copies of the manufacturer's instructions for use, supplied with the packaging of the device is not discarded at the point of use, but forwarded to the CSSD;
- Keeping copies of the manufacturer's instructions for use is included in the Quality System Controlled Document process for maintenance as a quality record; and
- Reporting inadequate or inappropriate instructions for use to the supplier or the manufacturer and the TGA through the IRIS reporting system.

B4. Purchasing Decisions

1. Introduction

Purchasing departments or product evaluation committees can directly influence the health risks associated with reusable medical devices by ensuring devices with appropriate design characteristics and reprocessing instructions are purchased and used within their facility. Information critical to making informed purchasing decisions may be obtained through consultation with the instrument supplier, the users of the device, the perioperative and CSSD staff, biomedical engineers and infection control staff. Issues such as the compatibility of the manufacturer's instructions for use with the cleaning, disinfecting and /or sterilization equipment used by the facility, reprocessing times and the quantities needed to meet demands [42] need to be taken into consideration to ensure informed purchasing decisions are made.

2. Consultation prior to purchase

Consultation between the purchasing department, the instrument supplier and perioperative, CSSD and infection control staff is essential to determine:

- Whether the CSSD has the appropriate equipment and qualified staff to undertake cleaning and reprocessing of the medical device in accordance with the manufacturer's instructions;
- If the instrument to be purchased is compatible with existing equipment, and can be decontaminated using procedures available within the facility[43];
- Any additional education or training of perioperative and CSSD staff is required: and
- The number of instruments required to meet operative demands.

In the absence of consultation on these issues, the perioperative and TSSU/CSSD personnel, when confronted with new medical devices may be forced into creating alternative methods for reprocessing. This type of "trial and error" approach may adversely affect the cleaning, disinfection, sterilization, integrity and performance of the device and may jeopardise any manufacturer's warranty particularly if the CSSD/TSSU does not or cannot follow the manufacturer's instructions for use. This can occur if the instructions for use are not reviewed prior to purchase and/or the facility does not have the required equipment to reprocess the device in accordance with the manufacturer's instructions.

3. Reprocessing timeframes

Purchasing departments or product evaluation committees also need to take into consideration the time required to reprocess medical devices, and the number of instruments required to be on hand to ensure the CSSD has adequate time to reprocess individual instruments. This is particularly important if the instrument will be required for repeated use within an operating/endoscopy session. If inadequate quantities are purchased, CSSD staff may be placed under pressure to resort to "short cuts" and compromise standard procedures and infection control guidelines to deliver the goods on time.

Furthermore, the continuous cycle of cleaning, high temperature sterilization and rapid cooling of instruments to allow rapid reuse may adversely affect the integrity of the materials used in the manufacture of the device and the longevity of the medical device. The manufacturer's warranty may also be jeopardised, particularly if this type of repeated use is contra-indicated.

4. Guidelines for purchasing instruments

The Expert Working Group recommend health care facilities have policies and guidelines for the purchase of medical devices to ensure equipment purchased is fit for the intended purpose, compatible with existing equipment, easy to clean and the processes to achieve decontamination are available within the organisation [41, 42, 43].

A suggested checklist for purchasing instruments, adopted from the Quality Task Force from the European Forum for Hospital Supply[44] is at Attachment B.

Part C:
Reporting and Investigating Potential Breaches Of Infection Control

1. Introduction
The true extent of transmission of infectious agents resulting from contaminated instruments is relatively unknown for a number of reasons as previously stated in the literature review.

Furthermore, incidents of potential contamination are not routinely reported to health authorities, and investigators of surgical site infections may not consider the instruments used during the procedure. Implementing a system of reporting and investigating incidents of potential breaches of infection control, providing feedback from the investigations and implementing corrective action will help identify the extent of the problem and reduce the risk of recurrence.

Health Authorities have well documented infection control guidelines for investigating incidents resulting in suspected or potential acquisition of blood borne viruses and outbreaks of communicable / infectious diseases in health care facilities [45, 46, 47, 48]. These guidelines could be extended to include breaches of infection control associated with potentially contaminated reusable instruments.

Implementing a vigilance system that includes the following features should significantly reduce repetition of similar incidents:
- reporting and investigating potential or actual breaches of infection control;
- providing feedback on the outcomes of the investigations;
- implementing recommendations from the investigations;
- taking corrective action; and
- monitoring the effectiveness of the program.

2. Adverse event reporting
In broad terms, incident or adverse event reporting is the communication of an incident or adverse event to those who are likely to provide or contribute to a constructive response. An effective reporting system accurately determines which events should be reported, and to whom, and provides a mechanism to make, act on, and track reports. It also allows for the tracking of corrective actions. Such a system not only prevents events from recurring in-house, but also has much broader ramifications. The reporting of events, the outcomes of investigations and the remedies implemented by an institution to health authorities allows potential systemic problems to be identified. Preventive measures can be instituted more broadly across a range of health care facilities, which can ultimately benefit the entire health care community[49].

The health care facility's Quality System should include measures for preventing and dealing with incidents or adverse events, whether they are caused by mistakes, medical device malfunction or a combination of these and other factors. Incident and adverse event reporting, both in-house and to external organisations are an important part of those measures.

3. What to report and to whom
Reporting is not the exclusive responsibility of any group of individuals. However, nurses, physicians, surgeons, TSSU/CSSD staff and biomedical engineers are those most likely to detect a problem and should always be involved in the initial investigation of any adverse event. In the case of reusable device cleanliness, problems are most likely to be detected by CSSD /TSSUs. In such cases, reports should be sent to the health care facility's quality or

infection control manager to record and investigate the event, as appropriate, and to coordinate reporting to external organisations such as the relevant State or Territory Health Authority, and the TGA.

Any incident that has or is likely to result in a breach of infection control should be reported to the appropriate Unit Manager and the Infection Control Team. Sometimes it is difficult to make a judgement as to whether a problem could lead to a serious event. In these cases one should err on the side of caution and report the problem. The Infection Control Team can then track the difficulties, and make appropriate approaches to the State or Territory Health Authority. When a medical device malfunctions or some aspect of medical device design is wholly or partly responsible for an incident, a detailed report should also be sent to the supplier or manufacturer and the TGA.

4. Investigations by health care facilities

A sample flow chart for investigating an infection control adverse event, incident or concern is shown in Figure 5. The key elements of a health care facility reporting system are outlined in Table 6.

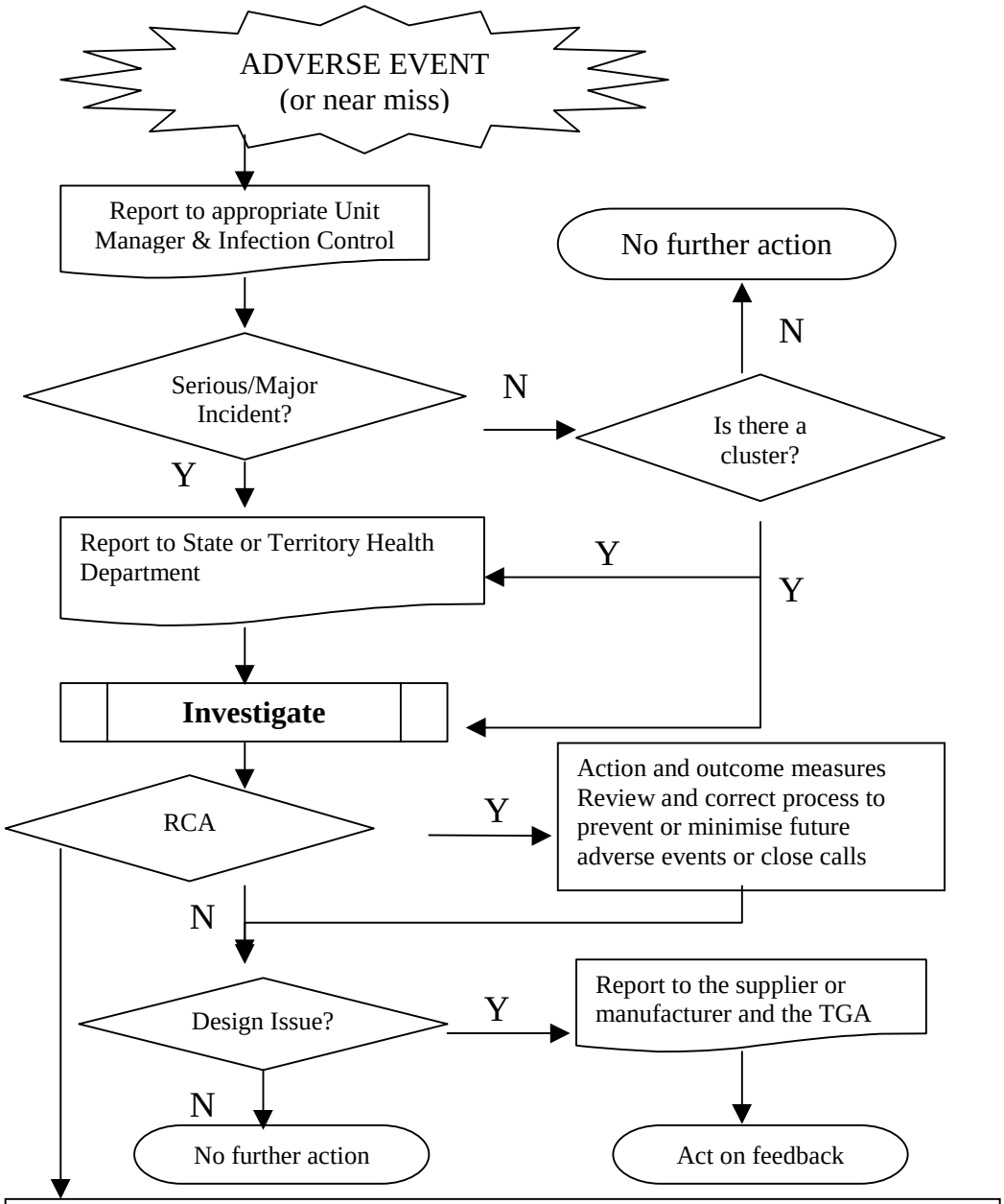
Any event or problem should first be reported to the appropriate Line or Unit Manager and Infection Control Team who should coordinate further action and communications. If the event or issue is not serious, it may be sufficient to log the problem and monitor for further occurrences. It is good practise to report minor medical device difficulties and malfunctions (if any) to the manufacturer.

If the issue is serious and may have major public health consequences, it should be reported to the State or Territory Health Authority and consideration should be given to what treatment or testing exposed patients should be offered.

Serious events control (see risk matrix for clarification of serious and major consequences) or "clusters" of minor events should be followed up by a thorough internal investigation to determine the root cause(s) of the breach as quickly as possible. Time is critical. It is important that hospital procedures include an immediate action plan for the investigation of these events. This action plan should include directions for:

- Preserving evidence (eg date and time of sterilization, the device involved, and digital photographs of the contaminated device may assist);
- Assembling an investigation team (eg clinicians **not** responsible for patient, CSSD Manager, Infection Control Manager and the Operating Room Manager);
- Collecting and reviewing information (patient and device related), including interviews with attending personnel at the time of the event (see sample internal incident reporting form at attachment C);
- Assessing the harm or the potential to cause harm;
- Reporting the incident to the State or Territory Health Authority; and
- Reporting the event to the supplier and the TGA.

Figure 5 Flow Chart for Reporting a Potential Breach of Infection Control



In line with the Root Cause Analysis literature, should 'Triage Questions' be used? (refer Veterans Affairs National Center for Patient Safety, NCPS Triage Cards) -

Human Factors

- Human Factors – Communications (issues related to communication, flow of information, and availability of information as needed)
- Human Factors – Training (issues related to job training, special training, and continuing education; including timing of training).
- Human Factors – Fatigue/Scheduling (scheduling, staffing issues)

Environment/Equipment

- Factors related to use and location of equipment; codes, specifications and regulations; general suitability of the environment

Rules/Policies/Procedures

- Assessing the existence and ready accessibility of directives including technical information.

Barriers

- Assess the effectiveness of barriers designed to protect people and property from adverse events.

Table 6 Elements of the reporting system

1. Initial decisions	• which potential breaches of infection control should be reported; • how the incident will be reported; • which reports will be investigated; and • how the investigation will be carried out.

2. Assign responsibilities	• who has overall responsibility for the reporting system;
	• who is responsible for:
	  • detecting and reporting incidents;
	  • cancelling procedures; and
	  • reviewing of stored instruments they are determined safe for use;
	• who should receive notice of a serious breach of infection control;
	• who should investigate the reported incident; and
	• who should review the findings and direct corrective action.

3. Information needed in an incident report **A Root Cause Analysis is recommended when investigating this type of incident**	• the contact details of the person writing the report; • details of the surgical or diagnostic procedure including time, date and staff members involved; • a complete description of the incident including what, how, when, where and why the incident occurred; • the identifying features of the device in question including the device name, supplier, catalogue number, batch/serial number, expiry date (if applicable); • details of the procedures followed to reprocess the device (sterilising service records); • details of contributing factors (eg instrument design, reprocessing timeframes, if the cleaning /reprocessing equipment was adequate); • clinical history of the patient /s affected (removing patient identifiers) • details of any post procedural infection and treatment prescribed; and • any corrective action taken.
4. When to report breaches of infection control to health authorities	• the breach involves possible contamination with diseases which have public health implications; • the breach involves a number of patients; • where the impact of the breach gives rise to a broader public interest, eg “look back” investigations; and • where there are implications for State or Territory policy development or adjustment in infection control and sterilization; • Routine regular reports including the number of incident reports including severity and likelihood of re-occurrence; and • any identifiable trends or patterns (eg same surgical team).
5. What to include in a report to the health authorities	• the likelihood of the incident affecting public health and safety; • the likelihood of the source patient/equipment being infectious; • the likelihood of the incident resulting in transmission of an infectious agent; • the public health benefit of reporting the incident; • the legal and policy obligations to report; and • whether a Root Cause Analysis was performed
6. Implementing recommendations or Corrective action	• disseminate outcomes of the investigations; and • ensure that the recommendations of Safety Alerts, Recalls or corrective actions to cleaning and disinfection process etc are carried out.
7. Ongoing monitoring	

* Adapted from the “World Health Organisation (WHO) Surveillance Of Adverse Events Following Immunisation Field Guide For Managers of Immunisation Programmes 1997.”

5. Investigations by State or Territory Health Authorities

When planning and implementing an investigation it is important to clarify who has responsibility at each level to avoid confusion and duplication.

Developing a risk matrix to assist in determining the seriousness of the incident and the type of investigation to be undertaken is also useful. The risk matrix used by NSW Health included as attachment D is a starting point for health authorities that currently do not have a system and are faced with conducting an investigation or developing a system for reporting and investigating incidents.

The following checklist for investigating incidents and the tips for dealing with media enquires may also provide a useful tool for those faced with an incident requiring investigation.

Table 7 Checklist for health authorities (only applicable if required to undertake an investigation)

- Develop standard procedures for investigating potential breaches of infection control associated with reusable instruments;
- Determine the membership of the investigation team eg physician, infection control, CSSD, microbiologist and public health physician;
- Designate and train staff to conduct investigations;
- Inform healthcare professionals and healthcare facilities of the need to report incidents;
- Formulate a hypotheses as to the cause of the incident in conjunction with the local investigation team;
- Review clinical findings;
- Review epidemiology findings;
- Summarise report findings;
- Recommend corrective action; and
- Communicate findings and incidents to all healthcare facilities.

Table 8 Communicating with the public and the media[50]

- Identify a spokesperson for public and medical communications;
- Decide if the report needs investigating and /or announcing to the public;
- Minimise the delay in response to the public and media;
- Prepare behind the scenes;
- Take the initiative and determine the key messages;
- Develop questions and answers in advance; and
- Don't over react and keep calm during the interview process.

6. Investigations by the TGA - Incident Report Investigation Scheme

The TGA Incident Report Investigation Scheme (IRIS) is responsible for the handling and investigation of all reports submitted to TGA on adverse events or problems associated with the use of medical devices. Approximately 600 reports are received annually mainly from nursing staff but also from suppliers, doctors, physicians, surgeons and biomedical engineers. The causes of problems are diverse but prominently feature mechanical or material failure, design, labelling, packaging or manufacturing errors, software deficiencies, device interactions and user/systemic errors.

On receipt, each report receives initial risk assessment by the IRIS Coordinator. If the problem is serious, then an investigation is initiated right away. Regardless of the outcome of this initial assessment, a panel of scientific, engineering and clinical experts assesses all reports. The panel recommends what level of investigation will take place. Reports that have led to or could lead to serious injury are given the highest priority. Unusual incidents that may have led to injury, or incidents that have unusually high levels of incidence are

investigated routinely. Isolated incidents or incidents that are not likely to lead to any injury or have a detrimental effect on patients or operators are not investigated. All reports are entered into a database so that they may be easily referenced in the future. Once a report has been recommended for investigation, it is assigned to the most appropriate qualified investigator.

The investigator will contact the distributor, and continue to work with the distributor and the reporter to resolve any issue. Reports are treated confidentially, and both the reporter and the distributor are informed of the outcome of the investigation. TGA has extensive experience and testing facilities that can be used in the investigation into reports of problems. Final outcomes may include recall, safety alert, product improvement, user education, compliance testing, referral to the Quality Systems and Licensing Section for follow up audits, and articles in the TGA News and other publications. The TGA provides the reporter of the incident with direct feedback of the outcomes and also exchanges information on significant incident investigations with overseas regulatory authorities.

TGA IRIS Medical Incident Reporting forms (included in the attachments to this report) are also available on TGA website at http://www.tga.gov.au. Although the use of the form is not compulsory it is recommended it be used as the basis of a minimum information set reported to the TGA to allow thorough investigation of an incident.

7. Putting the Pieces Together

Procedures for reporting of adverse events both in house and to outside organisations is a good start, but doesn't complete the picture. To obtain the full benefits from reporting incidents, a health care facility should have procedures in place whereby the recommendations from investigations conducted by the healthcare facility, the health authorities and the TGA are followed up and implemented. The Quality or Infection Control Manager, Product Coordinator or person responsible for coordinating and disseminating the incident reports may also be able to take responsibility for coordinating and disseminating safety warnings, recalls and other important information that result from investigations by the health authorities and the TGA.

References

A Literature review

1. Spaulding EH. Chemical disinfection of medical and surgical materials. In: Block SS, ed. *Disinfection, Sterilization and Preservation.* Philadelphia: Lea and Febiger, 1991:617-641.
2. Rutala WA. Selection and use of disinfectants in healthcare. In Mayhall CG, ed. *Hospital Epidemiology and Infection Control.* Philadelphia: Lippincott Williams &Wilkins, 1999:1161-1181.
3. Hand washing, cleaning, disinfection and sterilization in health care Volume 24S8 Canada communicable disease report infection control guidelines. 1998. http://www.hc-sc.gc.ca/hpb/lcdc/publicat/ccdr/98pdf/cdr24s8e.pdf Accessed 30/04/2003.
4. Weber DJ, Rutala WA. Managing the risk of nosocomial transmission of prion disease. *Curr Opin Infect Dis* 2002;15:421-425.
5. Cowen A. *Infection control in endoscopy.* Sydney: Gastroenterological Society of Australia, Report 1999.
6. Department of Health and Ageing, *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting*- Department of Health and Ageing 2004.
7. Muscarella LF. The benefits of ultrasonics cleaning. *Infection Control Today* 2001;5:42-44.
8. Maneulidis EE, Maneulidis L. Experiments on maternal transmission of Creutzfeldt-Jakob Disease in guinea pigs. *Proc Soc Exp Biol Med* 1979;160:223-6.
9. Duma R, Warner J, Dalton H. Septicaemia from intravenous infusions. *N Engl J Med* 1971;284:257-60.
10. Matsaniotis N, Syriopoulou V, TheodoridouM, Tzanetou K, Mostrou G. Enterobacteria sepsis in infants and children due to contaminated intravenous fluids. *Infect Control* 1984;5:471-77.
11. Birnie GG, Quigley EM, Clements GB, Follett EA, Watkinson G. Endoscopic transmission of hepatitis B virus. *Gut* 1983;24:171-4.
12. Bronowicki JP, Vernard V, Botte C, Monhoven N, Gastin I, Chone L, et al. Patient-to-patient transmission of hepatitis C virus during colonoscopy. *N Engl J Med* 1997;337:237-40.
13. O'Connor BH, Bennet JR, Alexander JF, Sutton DR, Leighton I, Maw SL, et al. Salmonellosis infection transmitted by fiberoptic endoscope. *Lancet* 1982;2:864-6.
14. Dwyer DM, Klein EG, Istre GR, Robinson MG, Neumann DA, McCoy GA. Salmonella newport infections transmitted by fiberoptic colonoscopy. *Gastrointest Endosc* 1989;25:102-3.
15. Parker HW, Geenan JE, Bjork JT, Stewart ET. A prospective analysis of fever and bacteraemia following ERCP. *Gastroint Endosc* 1989;25:102-3.
16. Struelens MJ, Rost F, Deplano A, Maas A, Schwam V, Serruys E, et al. Pseudomonas Aeruginosa and enterobacteriaceae bacteraemia after biliary endoscopy: An outbreak investigation using DNA macrerestriction analysis. *Am J Med* 1993;95:489-98.
17. Gorse GJ, Messner RL. Infection control practices in gastrointestinal endoscopy in the United States: A National Survey. *Infect Control Hosp Epidemiol* 1991;12:289-96.
18. Mandelstam P, Sugawa C, Silvis SE, Nebel OT, Rogers BHG. Complications associated with esophagogastroduodenoscopy and with esophageal dilation. *Gastrointest Endosc* 1976;23:16-9.
19. Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Int Med* 1993;118:117-28.

20. Doherty DE, Falko JM, Lefkovitz N, Rogers J, Fromkes J. Pseudomonas Aeruginosa sepsis following endoscopic retrograde cholangiopancreatography (ERCP). *Dig Dis Sci* 1982;27:169-70.

21. Earnshaw JJ, Clark AW, Thom BT. Outbreak of Pseudomonas Aeruginosa following endoscopic retrograde cholangiopancreatography. *J Hosp Infect* 1985;6:95-7.

22. Allen JI, Allen MO, Olson MM, Gerding DN, Shanholtzer CJ, Meier P et al. Pseudomonas infection of the biliary system resulting from use of a contaminated endoscope. *Gastroenterology* 1987;92:759-63.

23. Agerton T, Valway S, Gore B, Pozsik C, Plikaytis B et.al. Transmission of a highly drug-resistant strain (strain w1) of Mycobacterium Tuberculosis. Community outbreak and nosocomial transmission via a contaminated bronchoscope. *JAMA* 1997;278:1073-1077.

24. Michele TM, Cronin WA, Graham NM, Dwyer DM, Pope DS et.al. Transmission of mycobacterium tuberculosis by a fiberoptic bronchoscope. identification by DNA fingerprinting. *JAMA* 1997;278:1093-5.

25.–

26.–

27. Will RG, Matthew WB. Evidence for case-to-case transmission of Creutzfeldt-Jakob Disease. *J Neurol Neurosurg Psychiat* 1982;45:235-8.

28. Southwick KL, Hoffmann K, Ferree K, Matthews J, Salfinger M. Cluster of tuberculosis cases in North Carolina: possible association with atomizer reuse. *Am J Infect Control* 2001;29:1-6

29. Chant K, Kociuba K, Munro R, Crone S, Kerridge R, et.al. Investigation Of Possible Patient-To-Patient Transmission Of Hepatitis C In A Hospital. *NSW Public Health Bulletin.* 1994;5:47-51.

30. Heinsen A, Bendtsen F and Fomsgaard A. A phylogenetic analysis elucidating a case of patient-to-patient transmission of hepatitis C virus during surgery. *Journal of Hospital Infection* 2000;46:309-313.

B1 Instrument design

31. Hewitt A. Laparoscopic instruments: handle with care. *Infection Control Today* 2002;11. http://www.infectioncontroltoday.com/articles/2b1feat3.html Accessed 28/4/2003.

32. DesCoteaux JG, Poulin EC, Julien M, Guidoin R. Residual organic debris on processed surgical instruments. *AORN Journal.* July1995;62(1):23-30.

33. Dietz B, Kircheis U, Schwarz I, Martiny H. Freely accessible endoscopic channels improve efficacy of cleaning. *Endoscopy* 2001;33(6):523-528.

34. Phillips RA. Incidence of visible or occult blood on laryngoscope blades and handles, *AANA Journal*, June 1997;65(3):241-6.

35. Yang R, Ng S, Nichol M, Laine L, a cost performance evaluation of disposable and reusable biopsy forceps in GI endoscopy. *Gastrointestinal Endoscopy*, March 2000;51(3):266-70.

36. Rizzo J, Bernstein D, Gress F. A performance, safety and cost comparison of reusable and disposable endoscopic biopsy forceps: a prospective, randomised trial. *Gastrointestinal Endoscopy*, March 2000;51(3):257-61.

37. Lynn W. Time to design a new generation of surgical instruments, *Infection Control Today*. Dec 2001.http://www.infectioncontroltoday.com/articles/ Accessed 28/4/2003.

B2 Policies and Practices of Health Care Facilities

38. Department of Human Services. Infection control: *literature review*, Department of Human Services, Victoria, 1998:31-40. http://infectioncontrol.health.vic.gov.au/ Accessed 10/7/2003

39. Iischner C. Networking in central service. *Sterilization Aust* 1996;15:26-30. Quoted in Department of Human Services Infection Control: *literature review*, Department of Human Services, Victoria, 1998:31-40. http://infectioncontrol.health.vic.gov.au/infcon/dis.htm Accessed 10/7/2003

B3 Manufacturer's instructions

40. *The Therapeutic Goods Act 1989* (Cth), taking into account amendments up to Act No.39 of 2003, Canberra 2003 and the Therapeutic Goods (Medical Devices) Regulations 2002 (Cth).

41. *Sterilization of medical devices- Information to be provided by the manufacturer for the processing of resterilizable medical Devices* (ISO 17664:2003). Geneva: International Organization for Standardization, 2003.

B4 Purchasing decisions

42. Maresca TA, Wikander NJ, Beyond testing and repairing instruments, *Infection Control Today*, April 2003. http://www.infectioncontroltoday.com/articles/341inside.html Accessed 28/4/2003.

43. NHS Estates, A protocol for the local decontamination of surgical instruments, Department of Health, Department of Health, 2001.

44. European Forum for Hospital Supply Quality Task Group. Deciding how to process a new medical device. http://ww.dfhss.com/html/edu/qtg_006.php Accessed 30/4/2003.

Part C Reporting and investigation potential breaches of infection control

45. World Health Organisation, Surveillance of adverse events following immunization: *Field Guide For Managers Of Immunisation Programs*, World Health Organisation, Geneva, 1997.

46. Queensland Health, Extract from Infection control guidelines, Queensland Health, November 2001:280-285,330-340.

47. Public Health Division, Public health emergency management plan, Department of Human Services, Melbourne, Victoria. February 1998. http://www.dhs.vic.gov.au/phb/9808022/resp5.2.htm Accessed 28/4/2003.

48. Standards New Zealand, *Microbiological surveillance of flexible hollow endoscopes* (SNZ HB 8149:2001). Wellington, NZ:Standards New Zealand, 2002.

49. Medical device problem reporting for the betterment of healthcare, *Health Devices*, Vol 27 No 8, August 1998, 277-292. Quoted in Garcia, J E, "The investigation and reporting of medical device adverse events", Therapeutic Goods Administration.

50. World Health Organisation, Department of Vaccines and Other Biologicals, Informal meeting on issues of immunization data and monitoring: management of adverse events, Geneva 17-20 November1998, Session 8: Risk communication: dealing with the press and the public (WHO/V&B/99.06). Printed June 1999:22 Available from http:www.who.int/gpv-documents

General references

51. Accident and forensic investigation, in medical device reporting under the SIMA: A guide for health care facilities and manufacturers, pp 1 -12, ECRI, PA, USA 1996. Quoted in Garcia, J E, "The investigation and reporting of medical device adverse events", Therapeutic Goods Administration.

52. Medical Devices - Reporting adverse incidents and disseminating safety warnings, UK medical devices agency circular MDA SN200 1 (01) January 2001. Quoted in Garcia, J E, "The investigation and reporting of medical device adverse events", Therapeutic Goods Administration.

53. Centres For Disease Control, Updated guidelines for evaluating public health surveillance systems: recommendations for the Guidelines Working Group, *MMWR* July 2001 http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5013a1.htm accessed 28/4/2003.

54. Cowen A, Rayner T, King B, Jones D (eds). *Infection control guidelines in endoscopy*. Sydney, NSW: Gastroenterological Society of Australia, 1999.

55. Beyea SC. Reporting medical errors and adverse events. *AORN Journal.* April 2002;75.4: 853-55.

56. Standards Australia International, *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities* (AS/NZS 4187: 2003). Sydney NSW: Standards Australia International, Wellington, NZ: Standards New Zealand, 2003.

Appendix A: The IRIS Medical Device Incident Report Form

Health and Ageing

TGA THERAPEUTIC GOODS ADMINISTRATION

MEDSAFE NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY

The Australian and New Zealand Medical Device Incident Report Investigation Scheme

What is it? A medical device is any material instrument, apparatus, machine implement, contrivance, implant etc including any component, part or accessory which is used in health care and includes in-vitro diagnostics. The Scheme is a joint venture between the Australian Therapeutic Goods Administration and Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, intended to help maintain the standard of devices used in health care through voluntary co-operation between users, government and industry. It should be used in conjunction with local reporting channels. It provides an additional means by which unsafe products or procedures can be identified quickly so that appropriate action is taken.

Medical device users (clinicians, patients or their relatives, etc.) should use this form to report any suspected problems with a medical device which has or may present a health hazard. Reports originating in Australia should be sent to the Therapeutic Goods Administration and reports originating in New Zealand should be sent to the Ministry of Health.

What should be reported? Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or design. Suggestions for rectifying the problem or improving product performance would be appreciated.

What happens to your report? The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. If appropriate both Agencies will assess the issue and it may also be reported to other Health Authorities. If action is considered necessary it may involve any of the following: 1. Recall - removal of goods from sale or use, or their correction, for reasons relating to safety, efficiency or quality. 2. Safety Alert - urgent information to inform those responsible for the device, or affected by the problem. 3. Report in a TGA News Bulletin (a communication produced by the TGA and distributed in Australia and New Zealand to convey information on medical devices) or other appropriate journal(s).

Medical Device Incident Report

Form # UDIR01: For use by medical device users to report any suspected problem with a medical device that may create a health hazard. Medical device manufacturers or their authorised representative should use form # MDIR01.

A. Product Identification *(Provide all available details. Where * appears, delete whichever is not applicable)*

1.	Product Type/Application (eg Urinary Catheter)	
2.	Brand/Trade * Name and Model Number	
3.	Serial/Batch/Lot * Number	
4.	Date of manufacture / Date of purchase / Date of expiry / * AUST L or AUST R No.	
5.	Manufacturer's name address and telephone	
6.	Supplier's name address and telephone	
7.	Has the manufacturer been informed of the problem? Yes ☐ No ☐ If Yes, please supply the date and contact name	
8.	Is the product/packaging * available for inspection? Yes ☐ No ☐ *(please do not discard these items)*	

Important: Please fill in Sections B and C overleaf

Form # UDIR01. Last changed Dec 2002

B. Problem Description:

1. Consequences and history of problem:
(please Include history, circumstances, consequences and where relevant sketches or explanatory information)

C. Reporter Identification Do you want your identity to remain confidential? Yes ☐ No ☐

1.	Name			
2.	Position/ occupation			
3.	Dept AND Institution			
4.	Address			
5.	Telephone		Facsimile	
6.	E-mail		Date	
7.	Initial Reporter			
8.	Occ'n. and Dept at Instn.			
9.	Telephone		Facsimile	

D. Submitting the Form

In Australia:

Reply Paid 32
IRIS: Medical Device Incident Report Investigation Scheme
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606
AUSTRALIA

Fax Number: (02) 6232 8555,
E-mail : iris@health.gov.au
Urgent problems may be reported by
telephone to our **HOTLINE : 1800 809 361**

In New Zealand:

Compliance Team
Medsafe
Ministry of Health
PO Box 5013, Wellington
NEW ZEALAND

Fax Number: (04) 496 2599,
E-mail : trevor_nisbet@moh.govt.nz
Urgent problems may be reported by
telephone on **(04) 496 2364**

This form is available online at: www.tga.gov.au (TGA website) or www.medsafe.govt.nz (Medsafe website)

Appendix B: A checklist for purchasing reusable instruments

Device characteristics

[ ] Is the instrument easily recognisable as reusable as opposed to single use?
[ ] What is the limit on the number of times the instrument may be reprocessed?
[ ] Can the device be disassembled for cleaning and reprocessing?
[ ] Are there any features of the device that create difficulties for cleaning and reprocessing?
[ ] Will repeated reprocessing affect the integrity or longevity of the instrument?

Manufacturers instructions

[ ] Have the instructions for reprocessing been provided?
[ ] Are the instructions for reprocessing adequate?
[ ] Do the instructions include disassembly and reassembly?
[ ] Are there specific cleaning requirements?
[ ] Are accessory aids for cleaning provided or available?
[ ] Are there specific sterilization requirements?
[ ] Do the instructions offer alternative methods for cleaning, disinfection and/ or sterilization?

Capabilities of the facility to reprocess the device

[ ] Does the facility have the appropriate cleaning, disinfection and /or sterilization equipment?
[ ] Is the sterilization cycle specific for this device and has it been validated on-site?
[ ] Does the sterilization cycle require adjustments for this instrument?
[ ] If so, can these adjustments be conducted in the facility?
[ ] Can the instrument be serviced by the facility?
[ ] Is additional equipment required for the cleaning and reprocessing of the device?
[ ] Do staff require additional training to clean and reprocess the device?
[ ] What is the timeframe for reprocessing the device ready for reuse?
[ ] How frequently will this device be required in one operating session?
[ ] How frequently will this device be required in one operating day?
[ ] How many are needed to ensure they can be reprocessed within reasonable timeframes?

Warranty, repair and replacement services

[ ] What warranty is offered on the device?
[ ] Will the warranty be voided if an alternative method for reprocessing is used?
[ ] Does the device need to be returned to the manufacturer for servicing/ repair?
[ ] What are the timeframes for servicing and repair?
[ ] Does the supplier have replacement loan devices in the case of device failure?

Appendix C: An example Incident Report Form for healthcare facilities

Details of the facility and staff involved in the incident

Health care facility ……. ……..……

Address ……..……...

Procedure performed ……

Procedure room ……. Date of incident ……./……./…… Date reported ……./……./……

Staff involved……

Contact person ……. Contact Ph No: (….)…….

Patient details

1. Is the patient aware of the incident? Yes No Unknown
   If answered yes- has counselling been provided? Yes No Unknown
2. Has the patient presented with any symptoms? Yes No Unknown
   If answered yes, what was the diagnosis: ……..
3. Has the patient received testing? Yes No Unknown
   If yes, the tests requested were…….
4. Has the patient received post exposure prophylaxis or treatment? Yes No Unknown
   If yes, the treatment prescribed was:……
5 Patient's clinical history ……..……...…..

The incident

5. Was an instrument involved? Yes No Unknown
6. Is the instrument still in use? Yes No Unknown
7. Was the incident related to instrument design? Yes No Unknown
   If yes, was the incident reported to the TGA? Yes No Unknown
8. Was the incident a process-related issue? Yes No Unknown
9. Was the instrument cleaned and disinfected prior to use? Yes No Unknown
   If yes the type of disinfection was: (please circle)

   Heat disinfection Chemical disinfection Glutaraldehyde Ortho-phthalaldehyde

10. Was the instrument cleaned and sterilized prior to use? Yes No Unknown
    If yes the cycle and type of sterilization was: (please circle)

    Flash Pre-vacuum Downward displacement Gas plasma Peracetic acid

    Sterilization date..…../…../..… Time..…….. Cycle No.…….

Describe the incident relating to the potential breach of infection control:

……
……
……
……
……

Corrective action(s) taken to prevent recurrence:

……
……..

Appendix D:
Adaptation of the NSW Health Risk Matrix Severity Assessment Code

Figure 1 - Consequences Table

Serious	Major	Moderate	Minor	Minimum
Patients with death un-related to the natural course of the illness and differing from the immediate expected outcome of patient management or a re- processing incident where: • The device involved was used on a patient infectious for either a bloodborne viral illness or CJD and not sufficiently reprocessed before use on one or more subsequent patients. • The incident requires a lookback and results in the transmission of a life threatening infectious disease.	Patients with Major permanent loss of function unrelated to the natural course of the illness and differing from the expected outcome of patient management or a reprocessing incident where: • An insufficiently reprocessed device enters sterile tissue or contacts mucous membranes or non-intact skin on one or more subsequent patients • The incident may require a lookback and results in surgical failure (eg failed joint replacement/ amputation) or transmission of an infectious but curable disease.	Patients with Permanent reduction in bodily functioning unrelated to the natural course of the illness and differing from the expected outcome of patient management or a reprocessing incident where: • An insufficiently reprocessed device enters sterile tissue or contacts mucous membranes or non-intact skin in one or more subsequent patients. • The incident may require a lookback and results in surgical site infection, which requires additional surgery and limited return to full function eg. abscess formation, scarring, reduced range of movement.	• Patients requiring increased level of care following an unexpected increase in infections.	Patients with No injury or increased level of care or length of stay. • A load of insufficiently reprocessed devices are released for general use but the problem is identified and the devices recalled before being used on any patients.

Figure 2 – Likelihood Table

Probability Categories	Definition
Frequent	Is expected to occur again either immediately or within a short period of time
Likely	Will probably occur in most circumstances
Possible	Possibly will recur – might occur at some time
Unlikely	Possibly will recur – could occur at some time in 2 to 5 years
Rare	Unlikely to recur – may occur only in exceptional circumstances (may happen every 5 to 30 years)

Figure 4 – Action required Table

ACTION REQUIRED

- 1 = Extreme risk – immediate action required – A Root Cause Analysis (RCA) investigation must be commenced. In NSW a Reportable Incident Brief (RIB) must be forwarded to the DoH
- 2 = High risk – senior management attention needed – Notification to the DoH and / or RCA investigation is to be undertaken at the discretion of management. If RCA not undertaken, aggregate then undertake a practice improvement project
- 3 = Medium risk – management responsibility must be specified – Aggregate data then undertake a practice improvement project. Exception – all financial losses > 0 must be reported to senior management
- 4 = Low risk – manage by routine procedures – Aggregate data then undertake a practice improvement project

Figure 3 – SAC Matrix

CONSEQUENCE LIKELIHOOD	Serious	Major	Moderate	Minor	**Minimum**
Frequent	**1**	**1**	**2**	**3**	**3**
Likely	**1**	**1**	**2**	**3**	**4**
Possible	**1**	**2**	**2**	**3**	**4**
Unlikely	**1**	**2**	**3**	**4**	**4**
Rare	**2**	**3**	**3**	**4**	**4**

Appendix E: Glossary of Terms

Much of the terminology used in this document has been adopted from the *Infection control guidelines for the prevention of transmission of Infectious Diseases In The Health Care Setting"* Draft September 2002 (ICG) by the Australian Government Department of Health and Ageing.

Cleaning	The physical removal of foreign material, for example, dust, soil, organic material such as blood, secretions, excretions and microorganisms. Cleaning physically removes rather than inactivating microorganisms. Cleaning is accomplished with water, detergents and mechanical action. Cleaning must precede disinfection and sterilization.
Cluster	An infectious disease event that occurs with unusual frequency**.**
Contamination	The introduction of microorganisms or foreign matter (or both) to sterile or non-sterile materials or living tissue.
Creutzfeldt-Jakob Disease (CJD)	A progressive neurological disorder, one of the subacute Transmissible Spongiform Encephalopathies (TSEs) caused by prions. Clinical features of CJD include a progressive cerebellar syndrome, including ataxia, abnormalities of gait and speech, and dementia.
Critical site	Entry or penetrates into sterile tissue cavity or bloodstream. The instruments used must be sterile.
Decontamination	The process for the removal of microorganisms or foreign matter (or both) from contaminated materials or living tissue.
Disinfection	The inactivation of nonsporing microorganisms using either thermal (heat alone, or heat and water) or chemical means. See high level disinfection.
Health authorities	State and Territory Health Departments
Health care facility	Facilities that deliver health care services on a commercial or public health basis (eg hospitals, general practice, dentistry, community-based office practices, day-surgery centres, domiciliary nursing services, alternative health providers, and other community services such as needle and syringe programs).
Health care professional	Refers to all health care professionals, including students and trainees, and employees of health care facilities who have contact with patients or with blood or body substances from patients.
High-level disinfection	The minimum treatment recommended for reprocessing a device or item of equipment for use in a semi-critical site, if it cannot be sterilized. Objects will be free of microorganisms, with the exception of high numbers of bacterial spores.
Instrument container	Container in which instruments are stored
Instrument tray	A set containing multiple instruments that are used for specific procedures.
Lookback investigation	The process of identifying, tracing, recalling, counselling and testing patients or health care professionals who may have been exposed to an infection, usually a blood borne virus, due to a breakdown in infection control procedures or protocols.
Medical device	Any instrument, apparatus, appliance, material or other article, whether used alone or in combination (including the software necessary for its proper application), intended by the manufacturer to be used for human beings for the purposes of: • diagnosis, prevention, monitoring, treatment or alleviation of disease;

	• diagnosis, prevention, monitoring, treatment or alleviation of or compensation for an injury or handicap; • investigation, replacement or modification of the anatomy or of a physiological process; • control of conception; and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
Non-critical site	Body site with intact skin (but not mucous membranes). Instruments should be cleaned (manual or mechanical) and disinfected if necessary.
Notifiable disease	Disease or condition which is notifiable to State/Territory health department by legislation.
Patient	Includes (but is not limited to) a person who is accessing medical or health services, or who is undergoing any medical or health care procedure.
Reprocessing	All steps necessary to make a contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilization. References: • AS/NZS 4815:2001: *Office-based health care facilities not involved in complex patient procedures and processes - Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of the associated environment*, and • AS/NZS 4187:2003: *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*
Reusable item	An item designated or intended by its manufacturer as suitable for reprocessing and reuse. It is not a device that is designated or intended by the manufacturer for single use only.
Root cause analysis	*Root Cause Analysis* is one method of incident analysis. It is a logical, step by step process using a systems approach to determine the most basic (or root) cause and contributing factors of an adverse event or near miss. *Root Cause Analysis* aims to provide an understanding of how and why an event or near miss happened and to determine actions and recommendations, which when implemented will prevent the same or similar event from occurring in the future.
Semi-critical site	Intact mucosa or non-intact skin. Instruments having contact with a semi-critical site should be sterilized where possible, or high-level disinfected.
Sterilization	Destruction of microorganisms, including spores.
Suppliers	Companies (including manufacturers, importers or wholesalers) or individuals who market and supply the instruments to health care facilities and health care professionals.
Surgical instrument	Medical devices used in surgical and diagnostic procedures including endoscopic and minimally invasive procedures that are required to undergo sterilization or high level disinfection prior to use.
Unit manager	Is a general term that refers to the manger of a unit, ward, department or facility sometimes referred to as Nursing Unit Head or Line Manager. This includes for example the Manager of the Operating Room, CSSD, TSSU, X-Ray Department, a hospital ward, day Surgery Unit, or Clinic where surgery, endoscopic, dental or medical procedures are performed.

Appendix F: Acronyms

ACORN	Australian College of Operating Room Nurses
ARTG	Australian Register of Therapeutic Goods
CDC	United States Centers for Disease Control and Prevention
CJD	Creutzfeldt-Jakob Disease
CSSD	Central Sterilizing Supply Department
EEG	Electroencephalogram
ENT	Ear Nose and throat
EORNA	European Operating Room Nurses Association
ERCP	Endoscopic Retrograde Cholangiopancreatography
FSRACA	Federation of Sterilizing Research and Advisory Councils of Australia
HCV	Hepatitis C Virus
ICG	Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting" Draft September 2002
IFPN	International Federation of Perioperative Nurses
IRIS	Incident Reporting and Investigation Scheme
IV	Intravenous
MDEC	Medical Devices Evaluation Committee
NATN	National Association of Theatre Nurses
NCCTG	National Coordinating Committee on Therapeutic Goods
NSW	New South Wales
NZPNA	New Zealand Perioperative Nurses Association
ORNAC	Operating Room Nurses Association of Canada
RCA	Root Cause Analysis
SA	South Australia
SRACA SA Inc	Sterilizing Research Advisory Council of Australia (SA Inc)
SSI	Surgical Site Infection
TGA	Therapeutic Goods Administration
TSSU	Theatre Sterilization Services Unit
WHO	World Health Organisation