

Overview

This document

This document outlines the guidelines for the management of loan instrumentation for Sterile Services Departments / Units within New Zealand which are endorsed by the New Zealand Sterile Services Association [NZSSA].

These guidelines may be used to develop policies and procedures to improve day-to-day management of loan instrumentation within healthcare institutions to ensure effective management of these instruments so there is not a decline in the quality of service and ultimately in the quality of care for patients.

In recognition of the need to systematically manage the loan instrumentation, the NZSSA has adopted the following position:

- A partnership must be developed between the Sterile Services, the Operating Theatre and Supplier which is built on mutual trust and collaboration.
 - Healthcare facilities should provide Suppliers with information regarding time requirements for pre-procedure and post-procedure processing and these time requirements should be adhered to by the Suppliers.
 - Supplier should be able to provide specific instructions for processing of their instrumentation.
 - Sterile Services should keep a record of each set that is used, including time in and out and other processing specifics.
- There should be policies and procedures, created in collaboration with Suppliers, Sterile Services and Operating Theatres, to address the systematic management of loan instrumentation from acquisition to disposition which include the following:
 - Ordering & transportation in requirements
 - Check-in procedures
 - Pre-procedure processing requirements
 - Charging [if applicable]
 - Post-procedure processing requirements
 - Check out and transportation out requirements
- Staff responsible for the management of loan instrumentation must be trained and knowledgeable of all aspects of this process.

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Overview, Continued

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Introduction

Purpose

To establish a standardized format that can be used as a guideline to develop policies and procedures to systematically manage loan instrumentation.

Loan instrumentation would include items loaned from other healthcare facilities and Suppliers of specific surgical procedures as well as items consigned by a Supplier to a healthcare facility and stored in Operating Theatres for their use.

These guidelines place emphasis on developing a standardized system that will allow all involved parties to access information easily and understanding time requirements for pre-procedure and post-procedure processing so there can be understanding and agreement on item pick up and delivery times.

Scope

For use by Sterile Services, Operating Theatres and Loan Instrument Suppliers throughout New Zealand.

Associated documents

The table below identifies associated documents.

Type	Title/Description
Standard	<ul style="list-style-type: none"> AS/NZS 4187:2003 – Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.
Other	<ul style="list-style-type: none"> American Society for healthcare Central Service Professionals [ASHCSP] / International Association of Central Service Material Management [IAHCSMM] Position Paper on Loaner Instrumentation. 'Best Practice for the Loan Set Procedures': Joint project between the Medical Industries Association of Australia [MIAA] & the Sterilizing Research & Advisory Council of Australia [NSW] [SRACA]. Borrowing trouble: Loaner instrumentation poses big challenges. IAHCSMM Viewpoint November 2003 published in Healthcare Purchasing News. Position paper on management of loaner instrumentation and implants by the American Society for Healthcare Central Service Professionals. Presented at the 30th Annual Conference and Technical Exhibition 'Managing Quality in Changing Times' October 4 - 7, 1997.

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Introduction, Continued

Type	Title/Description
<p>Other, <i>continued</i></p>	<ul style="list-style-type: none"> • Guidelines for the use of loan sets: Perioperative Nurses Association of Queensland and the Sterilisation Research Advisory Council of Australia Queensland Inc. • Guidance Note – WorkSafe Victoria: Orthopaedic Surgical Instrument Sets – Reducing Risks of Musculoskeletal Disorders. • Infection Control Guidelines – Disinfection & Sterilisation: Queensland Health, Queensland Government, November 2001. • Needed: A process for loaner instruments. Marimargaret Reichert, Janet K Schultz. OR Manager. July 2002. Volume. 18. Issue 7. Pages 24 – 25. • Reducing Public Health Risks associated with Reusable Medical Devices: National Coordinating Committee on Therapeutic Goods Australia, May 2004. • The Borrowers – Tracking Loaner Instruments and Implants: ASHCSP / IAHCSMM Position Paper – October 1995 published in Materials Management in Health Care.

Background

The issue

Management of loan sets within health care facilities has long been recognised as a problem, not only in New Zealand but Internationally. It is a particular concern for sterile services personnel who are responsible for the decontamination, packing and sterilisation of loan sets to meet the requirements of theatre personnel who provide direct patient care.

As costs and sophistication of surgical instruments increase, it can be anticipated that the usage of loan sets will also increase. A high volume usage of loan instrumentation, short turn-around times and busy operating schedules place pressure on health care facilities and suppliers to have loan sets available at the scheduled surgical time.

Definition

Loans sets can be defined as:

‘a group of items used in an operation which is not owned by the hospital and will eventually be returned to the supplier’ and ‘includes surgeon’s own sets of instruments as well as powered tools, hip and knee replacement sets and sets borrowed from other healthcare facilities.

Objectives

- Expedite efficient distribution and handling of loan sets.
 - Minimise risk of all personnel engaged in the handling and use of loan sets.
 - Address specific issues or problems associated with the distribution, handling and / or use of loan sets.
 - Minimise the risk of contaminated sets being transferred between health care facilities or delivered back to suppliers.
 - Minimises misplaced or lost instrumentation.
 - Provide guidelines concerning booking practices, courier practices and packaging and presentation of sets.
 - Ensure all Standard / legal requirements are achieved.
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Background, Continued

Legislation Under legislation, health professionals are held responsible for providing patients with a ‘reasonable standard of care’ and this includes providing the ‘right equipment at the right time’ which has been processed according to appropriate Standards under which the health care facility operates.

Rationale Rationale for developing national guidelines includes:

- Every health care facility that deals with loan sets has the same problems.
- Every supplier has the same problems.
- Health care facilities are ultimately responsible for the safety of the patient and the healthcare worker, whether that be a sterile services technician or theatre personnel, therefore the health care facility should assume responsibility for assuring compliance with the Sterilisation Standards and the use of loan sets.
- Improve previous practices around the management of loan sets.
- A co-ordinated approach to the management of loan sets for all parties involved – theatre, sterile services and suppliers.
- Ensure AS/NZS 4187:2003 requirements are upheld.
- Responsibilities of health care facility and supplier must be clear.
- Standard guidelines would reduce comparison of processes between hospitals by surgeons thereby reducing the complaints Sterile Services receive.

Standards AS/NZS 4187 [Clause 12.4.3] establishes that a high standard needs to be attained in respect to the processing of loan instrumentation.

AS/NZS 4187

The Standard states:

- On receipt into the health care facility, loaned instruments *shall* undergo a complete routine cleaning and processing prior to sterilisation in a pre-vacuum or downward displacement sterilizer.
 - Loan instruments *should* not be ‘flash’ steam sterilized prior to use.
 - Lack of time *shall* not permit the cleaning process to be bypassed.
 - If soil and debris are found to be present on receipt of the instruments on loan, the condition of the instruments *shall* be reported to the supplier.
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Background, Continued

Standards AS/NZS 4187 *continued*

- Following use, all loaned instruments *shall* be subjected to the full cleaning process and sterilised as part of the decontamination process, before being returned to their source.

This level of processing ensures that an adequate level of control over the processing of loan sets is assured in each facility using them, and that the instruments are not being transported in an inadequately cleaned and potentially damaging state.

The Standard also states:

- Instruments on loan *shall* not be interchanged between human, necropsy and animal use.
- Due to problems in managing instruments on loan, there *should* be a contracted arrangement in place between the health care facility and the Supplier of instruments on loan, to define the responsibilities of the parties.

It is strongly recommended that reference be made to the article titled 'Loan sets – a 'joint' project of the FSRCA, MIAA, ACORN, Workcover'.

'Flash' Sterilization

AS/NZS 4187 [Clause 4.2.3] establishes when 'flashing' sterilization may occur.

The Standard states:

- The use of 'flash' sterilizers *shall* be restricted to situations where a single instrument has been dropped and there is no sterile duplicate available.
 - Cannulated, complex instruments, suction and other tubing *shall* not be processed by this method.
 - Can only be used for unwrapped, non-porous items.
 - The use of 'flash' sterilization as a convenience or as a cost saving mechanism is not acceptable. Having an adequate supply of instruments is more appropriate.
 - Where other types of sterilizers are used as instrument 'flash' sterilizers, the principles in this Clause continue to apply.
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Background, Continued

- General Issues**
- Often inadequate time for the loan set to be properly processed either before or after the intended surgical case, or both.
 - Uncertainty about the adequacy of instrument cleaning given in a previous facility.
 - Instruments are not always coded.
 - Coding is difficult to read.
 - Instrument does not have designated place in the box / tray [i.e. an extra instrument not usually supplied with the set has been included].
 - Instruments not in dedicated tray.
 - Instruments mixed with prostheses.
 - Paperwork does not always correspond to instruments and there is sometimes no logical sequence to some check lists.
 - Diagrams are sometimes provided, but are difficult to see [i.e. bad photocopy].
 - Metal trays often have broken clips.
 - Lids do not fit properly are sometimes jammed and broken.
 - No identifier i.e. Surgeon's name, date of surgery, type and side of surgery.
 - No indication of number of trays per set and number of shipping containers [i.e. 1 or 5 etc].
 - Mass of metal is too great to be sterilised as one tray.
 - Plastic trays not easily dried and results in wet loads and re-dos.
 - Plastic trays cracked or broken do not have holes in the bottom as required for the sterilizing process.
 - Dirty containers with layers of stickers baked onto cases.
 - Sets are large and often transported in container systems which impede steam sterilization and / or effective drying, meaning that the set of instruments needs to be completely repacked into smaller trays for wrapped sterilization in the facility.
 - Instruments are often specially designed and different from those usually processed within a health care facility, meaning that there may be delays as sterile services technicians learn to identify a new range of instruments.

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Background, Continued

Health & Safety Issues

- Weight of trays and volume of instruments within one tray have staffing implications.
 - There are sharp edges on instrument holders.
 - Weight of cases makes it difficult for couriers to handle them especially if the travel case does not have wheels. This is also an issue for sterile services personnel when moving full travel cases.
 - Improper decontamination of loan instrumentation can contaminate the receiving health care facility, sterile services technicians or patients with potentially infectious bio-hazardous materials, as well as the supplier's representatives handling the loan sets.
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Courier Issues

- No parking close to where delivery needs to be made.
 - No signage to show way to receiving docks.
 - Sterile Services are not expecting the loan equipment.
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Special Consideration

Creutzfeldt-Jakob Disease [CJD]

CJD and loan sets are an issue that needs special consideration. A loan set, used on a patient who is later found to have CJD, places patients at potentially more than one health care facility at risk.

Best Practice Guidelines

Health Care Facility – Operating Theatre

- Order loan instrumentation that allows sterile services one [1] full working day for reprocessing of the loan set before the procedure is scheduled and one [1] full working day after the procedure before returning to supplier.
 - When scheduling procedures, it is important to ensure the sterile services has sufficient time allocated to reprocess the loan sets before or between procedures. [Minimum of three [3] hours / Maximum of six [6] hours. Time is dependent on the number of trays and the complexity of the instruments to be reprocessed.]
 - It is important that in-service[s] given to sterile services as soon as possible after a decision is made to try a new loan set. Therefore, theatre personnel need to notify sterile services as soon as possible so an in-service session[s] can be arranged.
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Health Care Facility – Sterile Services

- Appoint a technician to be responsible for loan set co-ordination per shift for all communication purposes.
 - Ensures adequate staffing levels to support the initiative. The ability for sterile services to manage the extra work load associated with loan sets must be reviewed by health care facilities' senior management team and support sterile services by ensuring adequate FTE levels are available.
 - Develop and implement an education programme for all staff involved in the management of loan sets and new initiative.
 - Ensure health and safety guidelines for the health care facility and OS&H regulations in relation to manual handling are adhered to.
 - Develop and implement a robust booking process for loan sets in conjunction with suppliers and theatre.
 - Provide good communication concerning the status of loan sets. This can be managed via a whiteboard where the status of loan sets is updated daily to reflect additions and changes and the ability to add comments if required.
 - Any loan instrumentation found to be missing, contaminated or damaged on receipt at Sterile Services, will either be returned to the Supplier, at the Supplier expense, or will be decontaminated by Sterile Services and the Supplier will be invoiced for the costs of such decontamination.
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Best Practice Guidelines, Continued

Health Care Facility – Sterile Services *continued*

- Sterile Services will not accept loan instrumentation previously used on animals, cadavers or patients who are suspected of or have CJD / vCJD.
 - Develop and implement a robust checking in, processing and checking out procedures which would include:
 - Log receipt – date, time, signature of technician.
 - Perform inventory control check – verify types of instruments and quantities of instruments.
 - Perform quality assurance check – visually inspect instruments and implants for damage.
 - Inventory control sheet should follow the instrument set / sets through all the processes.
 - Follow the manufacturer’s written instructions for cleaning, packaging and sterilizing of instruments.
 - Check instruments for proper function – document problems, notify company and theatre immediately.
 - Reprocess instruments post use according to manufacturer’s instruments.
 - Verify instruments all present.
 - Check out process.
 - Ensure loan set is ready for pick up at prearranged time with the supplier or inform the supplier when the loan set is ready to be picked up. [Supplier arranges courier].
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Packaging and Presentation of Loan Instrument Sets

- Ordering and receipt of loan sets should allow sufficient time to permit in-house cleaning, packaging and sterilizing of the instruments before the scheduled surgery.
 - Instruments should always be coded clearly.
 - Instruments should be packed into dedicated boxes and any extra instruments should not be allowed to slide around loosely in the box but should be packaged separately and clearly labelled.
 - All instruments should be photographed and photos included in clear check lists with name of instrument, the item number and should be listed in sequence.
 - Have good graphics for ease of identification for sterile services technicians, in trays that can be sterilised and that are not too heavy or have a mass of instruments which cannot be sterilised within the tray provided.
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Best Practice Guidelines, Continued

Packaging and Presentation of Loan Instrument Sets *continued*

- Identify the boxes with information on:
 - How many boxes in each set [i.e. 1 of 5 etc]
 - The surgeon's name, date and time of surgery
 - Type and side of surgery
- The label should be removable and label and adhesive removed after EVERY use.
- Transport cases should be easily identified with company name and have ease of access.
- Transport cases need to be air tight and instrument trays wrapped in plastic.
- Trays should be packed to ensure ease of removal from the transport case.
- Trays should be thoughtfully packaged to enable ease of removal by sterile services technicians.
- Suppliers should attempt to source appropriately designed instrument trays / cases to meet the Australian & New Zealand standard practice for sterilization.
- All instrument sets should be checked for completeness and be cleaned and terminally decontaminated by placing through a sterilizer cycle before leaving the health care facility.
- Suppliers and health care facilities should ensure that courier companies are aware of particular requirements for transporting loan sets.

Heavy Sets

All employers have responsibilities under the Occupational Health and Safety Act to provide and maintain a safe and healthy workplace. Suppliers also have responsibilities to ensure their products can be handled safely. These responsibilities include ensuring that any risk of musculoskeletal disorders occurring is either eliminated or if it is not reasonable practicable to eliminate the risk, that the risk is reduced so far as is reasonable practicable.

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Best Practice Guidelines, Continued

Heavy Sets *continued*

Containers used for the delivery of loan sets should be strong, durable, waterproof and of as low a weight as possible. Where handles are fitted they should:

- Be cylindrical with a non-slip finish
- Have a diameter of about 20 to 40 mm
- Be at least 15 mm long and
- Have a clearance of at least 50 mm so that the whole hand can comfortably grasp the handle.

The containers should be on wheels and big enough for the task without being able to contain very high weights.

Loan Set Courier Service to and from the Health Care Facility

- A designated weather proof drop off area at the health care facility.
 - Prominent signage for access to the clean dock and to the operating theatre for drop off of implants.
 - A map of the hospital delivery bay and parking areas for courier service of loan sets should be made available to all loan set supply companies who in turn should supply these maps to the courier company and their drivers.
 - Good communication should be established between the loan set Supply Company, the courier service and the health care facility.
 - There should always be a person responsible for knowing that the loan set is being delivered, at what time and who will take delivery of same.
 - A good booking process should be introduced so that the courier knows exactly:
 - Where the transport cases are to be collected from
 - How many transport cases there are to the set
 - Exactly where they are to be delivered
 - What time they are to be delivered
 - Where they are to be collected from at the health care facility
 - What time they are to be collected from the health care facility
 - Health care facilities are responsible to ensure as far as practicable that couriers are not exposed to risks whilst accessing or egressing their property and for any safety issues whilst on site.
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Healthcare Facility Responsibilities

- Responsibilities**
- Ensures all their procedures comply with the requirements of AS/NZS 4187:2003 and all other applicable Standards.
 - Works with the supplier to ensure that appropriate implants, instruments and other equipment are supplied for the procedure being undertaken.
 - Ensures that, except in cases of genuine emergency, the supplier is given adequate notice of the date and time of the procedure.
 - Advises all relevant departments within the hospital [Theatre, Sterile Services, and Stores] in a timely manner of the date and time of the procedure, and the nature of the equipment that has been ordered.
 - Uses their best endeavours to maintain the integrity of the equipment while in their possession.
 - Checks instruments against supplier's inventory to ensure all items are accounted for, and that all items are clean and undamaged.
 - Checks items on receipt from the supplier, and advise the supplier of any irregularities.
 - In the event of receipt of soiled and / or contaminated instruments, the supplier is notified immediately.
 - Following use will clean and terminally sterilize loan instruments.
 - Ensures a 'decontamination and terminally sterilized certificate' accompanies the loan instrumentation when returned to the Supplier.
 - Ensures that instruments are adequately packaged for return to supplier.
 - Reviews the manufacturer's data and recommendations concerning dismantling, cleaning and sterilisation of instrumentation, ensuring the recommendations are understood and if not aligned with hospital policies or AS/NZS 4187:2003, to contact supplier to discuss issue with them.
 - Any 'incident' is reported to the relevant department, hospital or supplier at time of occurrence.
 - Arranges in-service for sterile services technicians for new instrumentation, in advance of the loan set being used in the health care facility wherever possible.
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Supplier Responsibilities

- Responsibilities**
- Ensures all their procedures comply with the requirements of AS/NZS 4187:2003 and all other applicable standards.
 - Works with the health care facility to ensure that appropriate implants, instruments and other equipment are supplied for the procedure being undertaken.
 - Ensures Implants are delivered directly to the Operating Theatre and are in a clean state with intact packaging and arrive inside clean transport cases lined with a clean plastic bag to guarantee sterility.
 - Prepares and supply an accurate checklist.
 - If any problems or discrepancies are identified, prior to dispatch, the Supplier must advise Sterile Services and the Charge Nurse of the Specialty requesting the loan instrumentation, of any possible delays.
 - Ensures that loan instrument[s] arrive within the agreed time frame of 24 hours before proposed surgical time.
 - Ensures that loan instrument[s] are adequately packaged for transport [e.g. instrument trays should be included in an outer road case].
 - Ensures that the quality, safety and efficacy of the instruments are maintained.
 - Checks instruments on return from the health care facility, and advises the sterile supplies department of any irregularities immediately.
 - In the event of receipt of soiled and/or contaminated instruments, inform the sterile supplies department immediately.
 - Ensures adequate inventory is available to support loan sets requirements to support agreed 24 hour time frame for health care facilities to receive instrumentation for processing prior to the surgical time.
 - Provides a copy of the last user's 'decontamination and terminally sterilized certificate' to the next user of the loan instrumentation.
 - Provides complete, comprehensive and validated written instructions for handling, cleaning, disinfecting, packaging, sterilising and, if applicable, aerating their products as well as identifying multi-port instruments.
 - Instructions are to written at all times – not given verbally.
 - Provides in-service concerning instrumentation supplied, prior to the loan set being used wherever possible.
 - Provides name of person who can be contacted with any queries.
 - Any manual additions or changes to a recipe are to be signed and dated.
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Proposed Flow for the Management of Loan Instrumentation

