

Voluntary Healthcare Agencies Risk Management Forum

Recommended Best Practice
for
Use of Reusable Invasive
Medical Devices (RIMDs)
on trial / or on loan to/from
other Hospitals and/or
Companies / Suppliers

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Introduction	Page 4	Updated to reflect Forum and National developments since document was issued in 2014.
Section 3 Bibliography	Page 7 Page 23	Updated to reflect the new ADR Regulations (2015)
Section 8.3.1.	Page 22	Consideration should be given (where feasible) to fitting transportation boxes with tracking devices (e.g. Radio Frequency Identifiers / barcodes).
Section 6.1 Bibliography		Updated to reflect HSE's National Medical Device Equipment Management Committee Supplier Deed in respect of the Loan of Medical Devices and Supply of Consignment Stock (2015).

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1. Introduction

Guidelines were initially developed in 2004 to standardise practices relating to the Loaning and Borrowing of RIMDs Devices between the Hospitals of the Dublin Hospitals Group Risk Management Forum and to assist Hospitals in minimising the risks associated with this practice.

The term Reusable Invasive Medical Devices (thereafter referred to as RIMDs) is now deemed appropriate for all surgical instruments, including endoscopy and dental instruments.)

This framework document developed in 2014 and updated in 2016 is based on best practice and reflects Irish and European Standards and Recommended practices and has been produced by a Working Group from members who have particular expertise in this area to minimise risk to patients arising from loaning and borrowing of RIMDs. This was submitted to the Forum Risk Management Executive and CEO Steering Committee for their consideration in consultation with Departments of Surgery and other relevant clinical specialities, Theatre Managers, Central Decontamination Unit Managers, Endoscopy Unit Managers, Sterivigilance and Infection Control Committees, Clinical Engineers, Quality and Risk Managers in member hospitals.

Developments since 2014 edition:

- This framework was adopted by the Quality Improvement Division of the HSE in its entirety for national application in 2015.
- The Forum's name changed to the "Voluntary Healthcare Agencies Risk Management Forum" from January 2016.
- The National Lead for the Decontamination Safety Programme, Quality Improvement Division of the HSE was invited by the Forum to participate in the 2016 review.

It must be stated at the outset that from a patient safety perspective, the loaning and borrowing of RIMDs should be strongly discouraged. The practice of loaning increases the risks associated with the decontamination of such RIMDs. However, in recognition of the reality that it may be necessary for RIMDs to be borrowed from other organisations and suppliers in order to improve patient outcomes, this framework outlines roles, responsibilities and necessary steps to be taken to maximise patient safety.

Healthcare Acquired Infection is the most common adverse event in Healthcare. Republic of Ireland National Report of the HPSC - The Point Prevalence Survey (November 2012) identified that Surgical Site Infection is the most common Healthcare Acquired Infection, experienced by patients resulting in increased bed days used as well as increasing liability for hospitals.

The risks associated with loaning and borrowing of RIMDs are:

- Significant Infection Control Risk to Patients (including vCJD) if unprocessed instruments/devices are used.

- Significant Patient Safety Risk if devices are used without due consultation with the Decontamination Unit/Clinical Engineering and without the necessary end user safety checks being performed on the RIMD prior to use.
- Moving and handling risks for healthcare staff and others involved in transportation such as taxi drivers.
- Patient and User safety risk associated with inadequate provision of time to identify compatibility of the RIMD to in house decontamination processes/ equipment, training, dismantling, and decontamination procedures.
- Patient and User safety risk associated with incompatibility of loan RIMD to accessories/ electrical devices currently used in the borrowing organisation.

Therefore the primary focus must be patient safety and one cannot assume that a borrowed RIMD is sterile or fit for purpose unless it is checked and reprocessed in the hospital in which it is to be used.

The effectiveness of decontamination is determined by all elements of the RIMD lifecycle, which need to be controlled and managed if decontamination is to be fully effective. Failure to adequately decontaminate RIMDs will increase the risk of transmission of infection between patients. Effective decontamination of RIMD is necessary to:

- maintain the functionality of RIMD,
- maintain integrity of biopsy specimens and
- protect the patient from the adverse consequences of non-sterile contaminants. (HSE Standards and Recommended Practices for Decontamination Units (2011V2.1)).

If it has been agreed that loaning, borrowing or trialing of RIMDs is deemed necessary and is appropriately authorised in accordance with local governance structures, these RIMDs must arrive allowing sufficient time to safely reprocess, in consultation with Theatre and CDU/EDU Managers. Specific consideration must be given for high volume, complex, unfamiliar RIMDs.

The Decontamination Unit must be provided with a decontamination certificate, loan kit contents and reprocessing instructions so that the RIMD can be reprocessed safely using standard decontamination processes.

Hospitals must have standard operating procedures in place based on this framework to manage the use of loaned /borrowed and trialed RIMDs to minimise the risks to patients, staff and others in accordance with local governance structures.

2. Objectives

- 2.1. To realise the benefits and opportunities afforded by participating in loan arrangements and equipment trials with suppliers, and at the same time identifying, and reducing the associated risks.
- 2.2. To develop a framework to be adopted in member organisations of the Voluntary Hospitals Risk Management Forum, that will be used both internally and shared with equipment suppliers, which fulfills 2.1 above.
- 2.3. To manage trial and “on loan” RIMDs in line with this framework and to restrict “unsolicited calling” by suppliers’ sales representatives.
- 2.4. To establish a monitoring and review mechanism, whereby this framework and local policies can be enhanced from time to time.
- 2.5. To ensure that any adverse findings associated with the improper use of any such RIMD are properly documented. Such information should be conveyed appropriately via member organisations’ local governance structures, highlighting the “issue/s”.

3. Explanation of Terms Used

ABBREVIATIONS:

- **ADR:** L'Accordeuropéen relatif au transport international des Marchandises Dangereuses par Route-**European Agreement Concerning the International** Carriage of Dangerous Goods by Road,
- **CSSD/ HSSU:** Sterile Services Department
- **DDU:** Dental Decontamination Unit
- **EDU :** Endoscopy Decontamination Unit
- **IMB:** Irish Medicines Board
- **HSE:** Health Service Executive
- **RIMD:** Reusable Invasive Medical Devices
- **vCJD:** Variant CreutzfeldtJakob Disease

The ADR Regulations (2015)

The ADR 2015 (European Agreement Concerning the International Carriage of Dangerous Goods by Road) states in 2.2.62.1.5.3 states:

“ .. For the purposes of ADR, infectious substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.”

“substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to the ADR unless they meet the criteria for inclusion in another class”.

Instruments which have been decontaminated either by chemical or thermal disinfection and have been drained of free liquid are exempt from ADR Regulation. “

Borrower

In the context of this document, the borrower refers to the hospital that borrows RIMD from another Hospital or Supplier.

Cleaning is the process that physically removes soiling including large numbers of microorganisms and the organic material on which they thrive.

Decontamination

Decontamination is the combination of processes (including cleaning, disinfection and Sterilization or high level disinfection) used to render RIMD safe for handling by staff and for use on service users. Effective decontamination of RIMD is an essential component in the prevention of healthcare associated infection.

Disinfection describes a process that eliminates many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial spores.

GIAI Coding Global Individual Asset Identifier. This is a form of GS1 coding and is globally unique to that individual asset/device.

GS1 Coding - Form of unique global standardisation for identification of a product.

High Level Disinfection - High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores.

HPSC

Health Protection Surveillance Centre

Invasive Device

A device, which in whole or in part, penetrates inside the body either through a body orifice or through the skin surface, is invasive. Invasiveness is generally categorised as invasive of a body orifice (including the surface of the eye), surgically invasive devices and implantable devices.

An implantable device is one which is intended to be totally introduced into the human body or to replace an epithelial surface or the surface of the eye by surgical intervention and which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

(Irish Medicines Board, 2009)

Lender

A Hospital or Supplier loaning RIMD's to another Hospital.

Loaning Register

A loaning register must be held by lender to record details of patients on whom RIMDs have been to ensure full traceability. See appendix 2.

Medical Device

For the purpose of the Medical Devices Directive 93/42/EEC 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 purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, 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 principal 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. ***(Irish Medicines Board, 2010)***

MS1

Medical Standard 1 is a type of electronic host database for RIMDs hosted via Cloud computing.

Sterilisation refers to a physical or chemical process that completely kills or destroys all forms of viable microorganisms from an object, including spores. Sterility is an absolute **condition - an item is either sterile or not sterile.**

(HSE Standards and Recommended Practices for Decontamination Units 2011 V2.1)

Supplier

Company who supplies RIMDs on loan or trial to a hospital.

4. Key Principles:

- 4.1 From a patient safety perspective, unnecessary loaning, borrowing and trialing of (RIMDs) should be strongly discouraged.
- 4.2 All RIMD's must be reprocessed using the manufacturer guidelines in accordance with ISO 17664:2004 "Sterilization of Medical Devices- Information to be supplied by the manufacturer for the processing of resterilizable medical devices" and be checked for compatibility with existing decontamination processes.
- 4.3 All RIMD's must be decontaminated both prior to and after use according to their classification of infection risk associated with their intended use (Table1) , allowing adequate time for the completion of this process(HSE Standards and Recommended Practice for Decontamination Units 2011 V2.1).

Table 1: Guide to classification of infection risk associated with the decontamination of RIMD

Risk	Application	Recommendation	<i>Examples *</i>
Critical	Items that enter sterile tissues/ sterile body areas or the vascular system	Requires sterilisation	<i>Surgical reusable invasive medical devices, biopsy forceps, laparoscopes, arthroscopes,</i> <i>Surgical dental RIMDs, e.g. forceps, elevators, luxators, scalers, surgical burs</i>
Semi-critical <i>(Not applicable to local dental decontamination services)</i>	Items in contact with mucous membranes or non-intact skin.	Sterilisation preferred but at a minimum, requires high level disinfection	<i>Flexible endoscopes,</i> <i>Specula,</i> <i>Respiratory therapy equipment</i>
Non-critical	Items in contact with intact skin but not mucous membranes or not in contact with the patient	Can be processed by cleaning (and low level disinfection where necessary)	<i>Blood pressure cuffs, oximeters, ECG leads, denture fabrication equipment, apex locators, impression material dispensers</i>

- 4.4 All loaned, borrowed or trialed RIMD's must be accompanied by relevant reprocessing instructions, list of contents and decontamination certificate. Where RIMD is new confirmation in writing that it has never been used is required from supplier in place of a decontamination certificate.

- 4.5 Both loaning and borrowing hospitals and suppliers must have standard operating procedures in place to allow RIMDs to be manually or electronically tracked through:-
- 4.5.1 The decontamination process in the loaning hospital / supplier prior to transportation to loaning hospital
 - 4.5.2 The decontamination process in the borrowing hospital prior to surgical/interventional procedure;
 - 4.5.3 The decontamination process in the borrowing hospital following the surgical/interventional procedure prior to return to hospital of origin/supplier;
 - 4.5.4 To the patient upon whom the RIMD(s) have been used , stored and to be made available to relevant stakeholders in the event of a look back being required in accordance with local governance arrangements.
- 4.6 All loaned RIMD's must be checked for functionality, given safety checks and repairs and signed off by relevant local technical expert (e.g. Medical Physics /Biomedical Engineer/ HSSU) in accordance with local governance arrangements.
- 4.7 Consignment RIMD's (i.e. on long term loan or trial) must be regularly serviced. The loaning company must regularly service their loan equipment and maintain a service history on this equipment and present this to the Theatre Manager or relevant local technical expert for verification in accordance with local governance arrangements.
- 4.8 Going forward, hospitals and suppliers may consider implementing GS1 coding to provide unique identifiers for RIMD sets as outlined by the HSE Standards and Recommended Practices for Decontamination (2011). The labeling of individual sets of RIMDs with Global Individual Asset Identifiers (GIAI codes) and uploading RIMD set details onto a host database (currently. MS1) will allow hospitals involved to electronically track and retrieve up to date checklists immediately. This also facilitates electronic tracking of RIMD sets through the decontamination process and to the patient on whom the loaned sets have been used.
- 4.9 The only circumstance where RIMDs don't have to be reprocessed prior to use in the borrowing hospital is where loaning hospital is accredited by the Irish Medicines Board as a sterilising entity and Transportation has been approved by ISO standard.

5. Recommendations

5.1 Each Voluntary Healthcare Agencies Risk Management Forum member draw up a hospital policy based on this framework, outlining the roles and responsibilities of CSSD/HSSU, Endoscopy Decontamination Units, Dental Decontamination Units, Theatre and Surgeons as relevant to their institution.

- In all instances of loaning and borrowing of RIMD's examples of relevant personnel who must be involved in the process:
Procurement Manager / Contracts Manager
- Medical Physics / Biomedical Engineer
- CSSD/HSSU Manager or equivalent
- Endoscopy Manager/ Dental Decontamination Unit Manager (if required).
- Relevant Theatre Sister/Senior staff nurse
- Relevant Surgical Team
- Suppliers/Companies

5.2 All suppliers require vendor approval, including appropriate **indemnity** based on the supplier meeting standard criteria. All borrowers should ensure that their property policies include the following wording:

Material Damage All Risks: ... *"On MACHINERY, PLANT and OTHER CONTENTS therein and in the open thereat including stock materials in trade, tenants improvements, furniture and fittings and All Other Contents the property of the Insured or held by them in trust for which they are responsible"*

*Please note that Voluntary Hospitals Risk Management Forum members who are part of the insurance group have this cover. Non insurance group members should ensure that their property policy has this provision.

5.3. All loan/trial RIMDs must meet MDD 93/42 EEC Article 17 requirements with reference to CE marking. A medical Device Questionnaire can be used in accordance with the Health Service Executive Medical Devices/Equipment Management Policy (2016).

5.4. A loaning register must be held by lender to record details of patients on whom RIMDs have been to ensure full traceability. See appendix 2.

5.5 A Service Level Agreement should be signed off by both company/supplier and relevant hospital managers in the borrowing/trialing hospitals.

5.5.1. The hospital requirements with respect to the borrowing or trialling of RIMD from the stated supplier should be documented in the SLA, to include the following

5.5.2. Logistical agreements for order placement, delivery and quality.

5.5.3. Agreed lead times for delivery and collection, documentation to be provided, training and after sales. In addition, the supplier must take responsibility for delivery of the agreed set of RIMD for the nominated procedure.

- 5.5.4. Service user requirements for example, Certs Training, Compliance to decontamination equipment and chemicals used.
- 5.5.5. Supplier must retain a record of patients MRN number on whom the RIMDs have been used to ensure full traceability and this information must be made available to hospitals upon request.
- 5.5.6. The requirement for the supplier to issue a signed dispatch note which states that the set is full and complete as per category listing agreed by the hospital and vendor.
- 5.6. This service level agreement is signed by the supplier and subject to annual or biannual review.
- 5.7 RIMD's borrowed between hospitals must be returned with a patient's MRN number on whom the RIMDs have been used to ensure full RIMD traceability. The MRN number should be the only piece of patient information returned.
- 5.8. A record of the borrowed RIMDs used must be documented in the patient's healthcare record.
- 5.9. It is recommended that this framework document is circulated to all the Suppliers that loan RIMD's to the Voluntary Healthcare Agencies Risk Management Forum member organisations.
- 5.10. Each hospital should develop and implement local policies and standard operating procedures for the practices of lending and borrowing of RIMDs as it relates to decontamination services and thereby safe patient care. Monitoring compliance should form part of routine auditing processes and may include checks on the documentation held by CNM's and Decontamination Managers relevant to the loaning, borrowing and trialing episodes. This auditing may also take the form of a "Look Back" exercise selecting specific cases and following the audit trail against the hospital's local policy on the loaning, borrowing and trialing of RIMD's.
- 5.11. Any deviation from local policy should be managed via internal governance structures. Corrective action plans should be put in place with ongoing review to ensure compliance, safe practices and that learning is shared.

6 Responsibilities and Obligations of Supplier loaning/trialling RIMDs

- 6.1 To realise the benefits and opportunities afforded by participating in loan arrangements and equipment trials, suppliers have a responsibility and obligation to undertake the following necessary control checks to protect the user and the patient in accordance with Irish Medicines Board requirements, Service Level Agreements with users and local governance arrangements in accordance with the HSE's National Medical Device Equipment Management Committee Supplier Deed in respect of the Loan of Medical Devices and Supply of Consignment Stock (2015).
- 6.2 **Vendor authorisation must be provided to the supplier in writing by borrowing/trialling hospital into order for the Supplier to loan RIMDs to the hospital.**
- 6.3 All loan/trial RIMDs must meet MDD 93/42 EEC Article 17 requirements with reference to CE marking.
- 6.4 **A Service Level Agreement should be signed off by both company/supplier and relevant hospital managers in the borrowing/trialing hospitals for all specified RIMDs.**
- 6.5 **RIMDs loaned or trialled that are outside those specified in existing Service Level Agreements must have prior written executive management approval to proceed in accordance with local governance arrangements.**
- 6.6 **The hospital requirements with respect to the borrowing or trialling of RIMD from the stated supplier should be documented in the SLA, to include the following**
- Logistical agreements for order placement, delivery and quality.
 - Agreed lead times for delivery and collection, documentation to be provided, training and after sales. In addition, the supplier must take responsibility for delivery of the agreed set of RIMD for the nominated procedure.
 - Service user requirements for example, Certs Training, Compliance to decontamination equipment and chemicals used.
 - The requirement for the supplier to issue a signed dispatch note which states that the set is full and complete as per category listing agreed by the hospital and vendor.
 - This service level agreement is signed by the supplier and subject to annual or biannual review.
 - All suppliers should provide proof of indemnity for public and product liability for minimum limit of indemnity of €6.5 million.

- 6.7 **RIMD's borrowed must be returned with a patient's MRN number on whom the RIMDs have been used on the Hospital's RIMD Loaning Register to ensure full RIMD traceability. The MRN number should be the only piece of patient information returned.**
- 6.8 All requests to loan/trial RIMD's must be made directly through relevant Theatre / Departmental Clinical Nurse Manager in the first instance
- 6.9 **RIMD's loaned or on trial to a hospital must be sent with the following relevant documentation:**
- Valid Decontamination Certificate or confirmation in writing that the RIMD is new and has never been used.
 - Tray content list (this should be an accurate list of actual contents **per tray** and not simply a list of all instruments supplied. Tray specification shall include product codes where available and photographic evidence where possible.)
 - Manufacturer's reprocessing instructions in accordance with ENISO:17664: 2004 ;
 - Any special requirements for assembly/ disassembly, lubrication or functional testing should be available
- 6.10 Training must be provided by the RIMD Supplier to Decontamination staff and users as required.
- 6.11 **To facilitate full tracking of decontamination processes and traceability of patients on whom RIMDs have been used, the supplier must maintain details of all records relating to the loaning/ of RIMDs and must be made available in the event of a look back exercise in accordance with local governance arrangements. This includes:**
- Name and description of the RIMD set as defined by supplier
 - RIMD unique identification number/ asset number (e.g. GS1 code)
 - Healthcare record number (MRN) of each and every patient that RIMD was used on. Name and position of person to whom the RIMD is lent
 - Name of the Hospital and specific department/theatre where RIMDs are sent.
 - Name and job title of the supplier representative who has/is loaned the RIMDs
- 6.12. Arrangements for the return of the RIMD must be made directly by the person who borrowed them, allowing sufficient time to safely reprocess, prior to return to the supplier in accordance with the Service Level Agreement. Specific consideration must be given for high volume, complex, unfamiliar RIMDs.
- 6.13. Responsibility for logging the safe and complete return of the RIMD rests with the designated Supplier Representative to whom the RIMDs are returned

7. Roles and Responsibilities in the Borrowing or Trialling of RIMDS

7.1. Roles and Responsibilities of Clinician/User in Borrowing Hospital

- 7.1 Clinicians/users have a responsibility and obligation to undertake the necessary control checks to protect patients, themselves and their organisations in accordance with Irish Medicines Board requirements, Clinical Indemnity Scheme and Service Level Agreements approved within local governance arrangements.
- 7.2 Liaise with relevant Clinical Nurse Manager in charge prior to arranging to bring RIMDs into their theatre/department,
- 7.3 Obtain Executive Management approval to proceed in writing in accordance with local governance arrangements prior to loaning/trailing RIMDs which are outside those specified in existing Service Level Agreements.
- 7.4 When arrangements are being made all reasonable steps must be taken to ensure Supplier provides RIMDs to the Decontamination Unit allowing sufficient time to safely reprocess, in consultation with Theatre and CDU/EDU Managers. Specific consideration must be given for high volume, complex, unfamiliar RIMDs.

7.2. Roles and Responsibilities of Hospital Management in Borrowing Hospital

- 7.2.1 Ensure that local governance arrangements are in place to ensure that there is a process to ensure Service Level Agreements are signed off by both company/supplier and relevant hospital managers in the borrowing/trialing hospitals for all specified RIMDs. This includes having appropriate indemnity within their property policy to include wording such as: Material Damage All Risks: ... "On MACHINERY, PLANT and OTHER CONTENTS therein and in the open thereat including stock materials in trade, tenants improvements, furniture and fittings and All Other Contents the property of the Insured or held by them in trust for which they are responsible". ** Forum members who are part of the insurance group have this wording. Non insurance group members should ensure that their property policy has this provision.*
- 7.2.2 Ensure local governance arrangements are in place whereby RIMDs loaned or trialled that are outside those specified in existing Service Level Agreements have prior written executive management approval to proceed.
- 7.2.3 The hospital requirements with respect to the borrowing or trialling of RIMD from the stated supplier should be documented in the SLA, to include the following
 - Logistical agreements for order placement, delivery and quality.
 - Agreed lead times for delivery and collection, documentation to be provided, training and after sales. In addition, the supplier must take responsibility for delivery of the agreed set of RIMD for the nominated procedure.

- Service user requirements for example, Certs Training, Compliance to decontamination equipment and chemicals used.
 - The requirement for the supplier to issue a signed dispatch note which states that the set is full and complete as per category listing agreed by the hospital and vendor.
 - This service level agreement is signed by the supplier and subject to annual or biannual review.
- 7.2.4 A copy of the local policy should be sent to the hospital's liaison person in Clinical Indemnity Scheme.

7.3. Roles and Responsibilities of Relevant Clinical Nurse Manager in the Borrowing Hospital

Prior to Surgical Intervention

- 7.3.1 Receives a request from the Operating Surgeon who has deemed that a loan or trial RIMD is necessary, in accordance with local approval/ governance procedures.
- 7.3.2 Place order for required RIMDs to include
- decontamination certificates,
 - list of each RIMD tray contents and
 - decontamination/ reprocessing instructions with supplier or loaning hospital
 - inform Decontamination Unit in writing (e.g. email).
- 7.3.3 All reasonable steps must be taken to ensure Supplier delivers RIMDs to the Decontamination Unit allowing sufficient time to safely reprocess, in consultation with Theatre and CDU/EDU Managers. Specific consideration must be given for high volume, complex, unfamiliar RIMDs.
- 7.3.4 In the case of borrowed endoscopes / electro medical devices Clinical Engineering or relevant local technical expert will also need to be contacted. On the arrival of loan RIMD to the borrowing hospital, ensure the equipment is checked by the supplier representative that it is correct and in appropriate list format for the hospital decontamination unit:
- Tray content list (this should be an accurate list of actual contents per tray and not simply a list of instruments in the set. Tray specification shall include product codes where available and photographic evidence where possible.)
 - Manufacturer's reprocessing instructions in accordance with ENISO:17664: 2006;
 - Any special requirements for assembly/ disassembly, lubrication or functional testing should be available.
- 7.3.5 Inform the supplier/ loaning hospital of any discrepancies regarding kit /documentation completeness.
- 7.3.6 Check that the borrowed RIMD kit contents match the set list immediately prior to use

- 7.3.7 Track the loan kit to the patient after the planned intervention.
- 7.3.8 Damaged or missing RIMDs must be inspected if required prior to use and inform Supplier / Loaning hospital of the discrepancy.
- 7.3.9 Cancellations of requirement to use loan RIMD Kits must be notified to the Decontamination Unit in writing as soon as possible.

7.4. Roles and Responsibilities of relevant Clinical Nurse in the borrowing hospital following Surgical Intervention

- 7.4.1 Immediately after use check the kit contents and identify what if any implants etc. have been used. Document this on the set list provided and return to Decontamination Unit.
- 7.4.2 All reasonable steps must be taken to ensure RIMDs are safely reprocessed, prior to being collected by the supplier or returned to loaning hospital, in consultation with Theatre and CDU/EDU Managers. Specific consideration must be given for high volume, complex, unfamiliar RIMDs.
- 7.4.3 In the event of RIMDs being in contact with patients or procedures suspected of having vCJD, such instrumentation should be identified and quarantined in accordance with HPSC Guidelines.
- 7.4.4 Following confirmation from Decontamination Unit Manager that Borrowed RIMDs are ready for return, inform Supplier or make appropriate transportation arrangements for their safe return to the loaning hospital.
- 7.4.5 Ensure the loan kit is appropriately containerised for collection.

7.5. Roles and Responsibilities of relevant Decontamination Unit Manager in Borrowing Hospital Prior to Surgical Intervention

- 7.5.1 On arrival of loan RIMD to the borrowing hospital the Theatre Rep together with the Decontamination Unit Rep must check that the contents of the loan kit and documentation necessary for reprocessing are correct for the planned intervention, this includes:
 - Valid Decontamination Certificate
 - Tray content list (this should be a list of actual contents per tray and not simply a list of instruments in the set. Tray specification shall include product codes where available and photographic evidence where possible.)
 - Manufacturer's reprocessing instructions in accordance with ENISO:17664: 2006;
 - Any special requirements for assembly/ disassembly, lubrication or functional testing should be available.

- 7.5.2 Inform Theatre Manager of any discrepancies identified with the documentation which may result in a delay in processing the loaned RIMDs.
- 7.5.3 Generate tracking label to allow the loan kit to be tracked through the decontamination process and thereby to the patient on whom the loan kit is to be used.
- 7.5.4 Check kit contents against the set list.
- 7.5.5 Inform Theatre Manager of any discrepancies identified with the loan kit such as damaged or missing instruments which may result in a delay in processing the loaned RIMDs.
- 7.5.6 Damaged or missing RIMDs must be inspected by Relevant Theatre Manager / Supplier.
- 7.5.7 Process RIMDs according to local policy and procedure.

7.6. Roles and Responsibilities of relevant Decontamination Unit Manager in Borrowing Hospital following Surgical Intervention

- 7.6.1 Check kit contents and clean, disinfect and sterilise / high level disinfect RIMDs after use in accordance with manufacturer's instructions. Instruments must remain in their designated set.
- 7.6.2 Complete and sign a decontamination certificate and attach all tracking / batch labels to the decontamination certificate.
- 7.6.3 Keep a copy of the decontamination certificate on site.
- 7.6.4 Inform relevant Theatre Manager that the loan kit is ready to be returned to Supplier.
Loaning hospital
- 7.6.5 In the event that the borrowed RIMDs are being returned directly from Decontamination Unit, ensure the loan kit is appropriately containerised for collection.

8. Management of Inter Hospital Loaning of RIMDS

8.1. Roles and Responsibilities of Relevant Clinical Nurse Manager in Loaning Hospital

Prior to Loaning RIMD

- 8.1.1 All requests to borrow RIMD's must be made directly by a relevant Clinical Nurse Manager from the requesting Hospital to the Clinical Nurse Manager or person in charge of the unit in the hospital which owns the RIMD.
- 8.1.2 Loaned RIMD's must be accompanied by relevant documentation as follows:
- Valid Decontamination Certificate
 - Tray content list (this should be an accurate list of actual contents per tray and not simply a list of instruments in the set. Tray specification shall include product codes where available and photographic evidence where possible.)
 - Manufacturer's reprocessing instructions in accordance with ENISO:17664: 2004 ;
 - Any special requirements for assembly/ disassembly, lubrication or functional testing should be available.
- 8.1.3 Details of all RIMD's which are loaned to another Hospital should be captured (e.g. entered into a log book (Appendix 3) or electronically scanned):
- Name and description of the RIMD set as defined in CDU/Theatre/ EDU/DDU
 - RIMD unique identification number
 - Name and job title of person to whom the RIMD is being loaned
 - Name of the Hospital and specific department/theatre where RIMDs are being sent
 - Name and job title of the person who is making the loan

8.2. Roles and Responsibilities of Relevant Clinical Nurse Manager in Loaning Hospital Following Surgical Intervention in the borrowing hospital

Arrangements for the return of the RIMD must be made directly with the person who borrowed them allowing sufficient time to safely reprocess, prior to return.. Specific consideration must be given for high volume, complex, unfamiliar RIMDs.

- 8.2.1 Responsibility for logging the safe and complete return of the RIMD rests with the Relevant Theatre Manager /designated person to whom the RIMDs are returned. The return date with the name of the Hospital and person returning the set must be indicated in the log or electronic tracking system, together with the RIMD details and confirmation of receipt of the decontamination certificate.
- 8.2.2 All returned RIMD's must be sent to Decontamination Unit for cleaning, disinfecting and sterilising prior to return to normal circulation.

.8.3 Transportation

8.3.1 All RIMDs must be decontaminated prior to transportation.

8.3.2 To ensure RIMDs are not damaged during transportation it is recommended that all hospitals should transport RIMD in a locked leak proof, puncture proof, rigid container, e.g. the UN approved containers such as those detailed below. Separate arrangements may be made for transportation of flexible endoscopes in accordance with manufacturers' instructions. Consideration should be given (where feasible) to fitting transportation boxes with tracking devices (e.g. Radio Frequency Identifiers / barcodes).



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Appendix One – Sample Decontamination Certificate

THE DECONTAMINATION CERTIFICATE

HOSPITAL NAME

Address

Contact Number

Preparation of RIMD for use on a patient, is the responsibility of the Hospital (user) borrowing the RIMD. These items have undergone a complete cleaning, disinfection and sterilisation process.

PLEASE TREAT AS CLEAN AND DISINFECTED ONLY

THIS RIMD IS NOT FIT FOR INTERVENTIONAL USE ON A PATIENT UNLESS IT IS REPROCESSED IN THE RECEIVING HOSPITAL PRIOR TO USE.

TO:

(Hospital, Company, Recognised repairer)

Returned to Owner/Company Loaned For Repair

Name and Description of RIMD: _____

No. of Trays: _____

The items listed above have been processed by the following method (in accordance with manufacturer's instructions

- | | |
|----------------------------------|--------------------------|
| 1. Manual washing | <input type="checkbox"/> |
| 2. Automated Washer/Disinfection | <input type="checkbox"/> |
| 3. High Level Disinfection | <input type="checkbox"/> |
| 4. Sterilisation | <input type="checkbox"/> |

PRINT Name of person releasing items: _____

Position: _____ Department: _____

Date: _____ Signature: _____

Appendix Two – Sample RIMD Loaning Register

RIMD LOANING REGISTER

Section A: LENDER
(Please complete when loaning RIMD to another hospital)

TO _____
(Name of hospital, to whom RIMD is being loaned)

CONTACT PERSON _____

DESCRIPTION _____

ASSET/I.D. NO. _____

ACCOMPANYING DOCUMENTS:

Contents Description

Decontamination Certificate

Reprocessing Instructions - (*Disassembling & assembling instructions*)

Date Released: _____ Signed: _____ Position: _____

Date of Return: _____ Signed: _____ Position _____

Section B: BORROWER
(Please complete when returning borrowed RIMD(s) from another hospital)

FROM: _____ CONTACT PERSON: _____
(Name of Hospital)

DESCRIPTION: _____

MRN MBER: _____

ASSET/I.D. No: _____

ACCOMPANYING DOCUMENTS:

Contents Description

Decontamination Certificate

Reprocessing Instructions - (*disassembling & assembling Instruction*)

Date Released: _____ Signed: _____ Position _____

Specify trays used on the patient: Use tray unique identifier (e.g. name, GS1 code / other):

Appendix Three – Sample Loan RIMD Checklist

LOAN RIMD CHECKLIST

**PLEASE COMPLETE AND FILE WITH
ATTACHED DECONTAMINATION CERTIFICATE IN THE LOAN RIMD BOOK**

Patient Number on Whom the RIMD was Used.

Date Received		Name of RIMD	
Loan Company/ Hospital		Number of Trays	
Disassembly Instruction? Cleaning Instructions Received		Is Decontamination Certificate Attached?	
Cleaning Instructions?		RIMD List Received?	
RIMD Check Complete?		Information and RIMD Contents Correct?	
Are cleaning instructions compatible with CDU?		When have the sets to be returned?	
When are the sets needed?			

If the answer to any of the above is No, please detail here and identify corrective action if required.

		Customers Informed?	
Date Processed in CDU			
Date Re Processed in CDU			
Decontamination Cert Complete?			
Signature		Date	

Appendix Four – Loan Set Management Principles between Suppliers/Manufacturers, Theatres & Decontamination Units

Loan Set Management Principles between Suppliers/Manufacturers, Theatres & Decontamination Units

Appendix
4



