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

March 2024

Beaumont Hospital • Central Remedial Clinic • Children's Health Ireland • The Coombe Hospital • Dublin Dental University Hospital • Incorporated Orthopaedic Hospital, Clontarf • Leopardstown Park Hospital • Mater Misericordiae University Hospital • Mercy University Hospital • Milford Care Centre, Limerick • National Maternity Hospital • National Orthopaedic Hospital Cappagh • National Rehabilitation Hospital • Our Lady's Hospice and Care Services • Peamount Healthcare • Rotunda Hospital • Royal Hospital Donnybrook • Royal Victoria Eye and Ear Hospital • St. Francis Hospice • St. James's Hospital • St. Michael's Hospital • St. Vincent's University Hospital • St. Vincent's Hospital, Fairview • St. John's Hospital, Limerick • South Infirmary Victoria University Hospital, Cork • Tallaght University Hospital

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Page 10	Additional objective to include requirement to report risks, incidents and near misses
Page 11	Abbreviations list updated
Page 16	Expanded wording relating to vendor agreements and indemnity
Page 19	Clarified supplier requirements re traceability of RIMD loaned
Page 31	Appendix 4 – Loan RIMD Checklist updated
	Minor edits / rewording to improve clarity throughout
	References updated throughout document and in bibliography

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Foreword

About the Voluntary Healthcare Agencies Risk Management Forum

The Dublin Hospitals Insurance Group

In 1992, The Department of Health brought eleven Voluntary Hospitals within the Dublin area, together for the purpose of collective purchasing of insurance *(known as the Dublin Hospitals Insurance Group).* These hospitals included: Adelaide Hospital, Beaumont Hospital, Cappagh National Orthopaedic Hospital, Mater Misericordiae University Hospital, National Rehabilitation Hospital, St. James's Hospital, St. Michael's Hospital, St. Vincent's University Hospital, Temple St Children's Hospital, The Meath Hospital, The National Children's Hospital, Harcourt St.

The Adelaide Hospital, along with the Meath Hospital and the National Children's Hospital, amalgamated when Heads of Agreement produced by a Department of Health Working Party were agreed by the Boards of the three base hospitals in May 1993,[1] therefore reducing number of member agencies to nine. The Adelaide and Meath Hospital incorporating the National Children's Hospital [2] opened at Tallaght in June 1998.

Establishment and Expansion of the Risk Management Forum

The Dublin Hospitals Risk Management Forum was established in July 1994 with a brief to review, monitor and co-ordinate the risk management activities in the Insurance Group.

Since its establishment, the Voluntary Hospitals Risk Management Forum has been instrumental in addressing a wide variety of risk management issues and where appropriate, has produced a variety of guidance documents for consideration and implementation by member organisations.

Membership was extended to all Dublin Voluntary Hospitals in 2007, increasing the membership to 22 hospitals. In 2011 eligibility for membership was extended to all organisations known as "section 38 agencies" and to some "section 39 agencies"[3] (together or otherwise referred to as "Voluntary Healthcare Agencies") increasing the membership to 26.

The Voluntary Hospitals Risk Management Forum changed its name to the Voluntary Healthcare Agencies Risk Management Forum (the "VHARMF") from 1st January 2016, in recognition of the various types of member organisations.

The Children's Health Act 2018[4] provided for amalgamation of Our Lady's Children's Hospital, Crumlin, Temple Street Children's University Hospital and the National Children's Hospital at Tallaght and the three hospitals became a single legal entity Children's Health Ireland (CHI)

[1] https://www.lenus.ie/bitstream/handle/10147/574984/managementreportingcontrolserviceplanningfinancialpositionofthehospital.pdf?sequence=1&isAllowed=y
[2] http://www.irishstatutebook.ie/eli/1996/si/228/made/en/print
[3] Section 39 agencies can be identified as they are bodies that receive funding from the HSE pursuant to section 39 of the Health Act 2004.

[4] http://www.irishstatutebook.ie/eli/2018/act/27/enacted/en/print#sec1

in 2019, reducing the number of member agencies to twenty-five. The Mercy University Hospital joined in November 2022, increasing membership to twenty-six member agencies.

As of January 1st, 2020, the VHARMF operates as an Unincorporated Association and is governed by the CEO Governance Group, comprising Chief Executive Officers of member agencies, which sets the strategic and operational objectives of the VHARMF. CEOs may nominate individuals to sit on various Sub-committees and Advisory groups determined by CEO Governance Group.

Object

The object of the Forum is in an efficient, transparent and fair way:

- to review, advise on, and co-ordinate risk management activities of its members;
- to agree a collective approach in managing agreed risks;
- to engage in shared learning;
- to make recommendations and produce guidance documents for members where appropriate;
- to procure insurances and other goods and services as may be required, all within a culture of cooperation, engagement and shared learning, whilst seeking and ensuring value for money for its members, while adopting best practice and complying with the legal obligations of the members.

Membership

All Voluntary Healthcare Agencies in the Republic of Ireland that report to their own Independent Boards/Boards of Directors are eligible to apply for membership of the VHARMF. Where the status of a member may change because of mergers/collaborations the locus of corporate responsibility for risk will determine eligibility for membership.

Member Voluntary Healthcare Agencies as of March 2024:

1. Beaumont Hospital
2. Central Remedial Clinic
3. Children's Health Ireland
4. Clontarf Hospital (Incorporated Orthopaedic Hospital of Ireland)
5. The Coombe Hospital
6. Dublin Dental University Hospital
7. Leopardstown Park Hospital
8. Mater Misericordiae University Hospital
9. Mercy University Hospital
10. Milford Care Centre
11. National Maternity Hospital
12. National Orthopaedic Hospital, Cappagh
13. National Rehabilitation Hospital
14. Our Lady's Hospice and Care Services
15. Peamount Healthcare
16. Royal Hospital Donnybrook
17. Royal Victoria Eye and Ear Hospital
18. South Infirmary Victoria University Hospital

19. St Francis Hospice
20. St. James's Hospital
21. St. Michael's Hospital
22. St. Vincent's University Hospital
23. St. Vincent's Hospital, Fairview
24. St. John's Hospital, Limerick
25. Tallaght University Hospital
26. The Rotunda Hospital

Committee Structure

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, 2018, 2021 and 2024 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 originally 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, Sterivigilence and Infection Prevention and Control Committees, Clinical Engineers, Quality and Risk Managers in member hospitals.

Developments since 2014 edition:

- This framework was adopted by the then HSE National Quality Improvement Team in its entirety for national application in 2015.
- The Forum's name changed to the "Voluntary Healthcare Agencies Risk Management Forum" from January 2016.
- HSE National Decontamination Advisor and QI Facilitator, Quality and Patient Safety Directorate was invited by the Forum to participate in the 2016, 2018, 2021 and 2024 reviews.

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 borrowing and loaning between organisations increases risks to patients 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 (December 2018) identified that Surgical Site Infection is the second 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 or implant is sterile or fit for purpose unless it is checked and reprocessed in the hospital in which it is to be used. Decisions to not reprocess loaned RIMD's prior to being used on patients should only be made in accordance with local governance arrangements and hospital protocols

Implantable Devices

Additionally, in accordance with MDR 2017/745, any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.

The focus of this document relates to the loaning and borrowing of Reusable Invasive Medical Devices. However, it is recognised that Implantable Devices, intended to be used alone or in combination with RIMD that are on loan, borrowed or on trial need to be controlled to ensure the implant is sterile and fit for purpose. Therefore, the 2021 edition of this Framework has provided high level principles for consideration when developing local policies pertaining to loaning and borrowing implantable devices.

The Medical device Regulation (2017/745), categorises medical devices into four risk classes based on their risk to patients. Implantable devices are classified under the Regulation as Class IIb and Class III medical devices which carry the highest risk to patients. It is critical that the management of implants is carried out in compliance with the Medical Device Regulation (2017/745) which requires the provision of clear and easily accessible essential information on implant devices to patients including clear identification of the implant.(HSE, HPRA, 2021). https://www.hse.ie/eng/services/publications/pp/medical-device-regulations.html. *(Both MDR guidance documents are referenced in the bibliography.*

All medical devices including implants must be CE marked, with some notable exemptions as per the HSE Patient Safety Alert: Medical Device Regulation and CE Marking(October 2023) https://assets.hse.ie/media/documents/NPSA_-_Medical_Device_Regulation_and_CE_Marking_aAYPMyG.pdf

Clinical Staff in theatre need to be aware of the classification of approved implants being used in accordance with local governance arrangements, risks of use and the requirement to adhere to the MDR manufacturing instructions.

Please see Appendices six and seven for further details.

The effectiveness of the decontamination process is determined by all elements of the RIMD lifecycle, which need to be controlled and managed if decontamination is to be fully effective. Failure of the user to appropriately 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 Central Decontamination Units –(2024, V3).

If it has been agreed that loaning, borrowing or trialling of RIMDs is deemed necessary and is appropriately authorised in accordance with local Medical Device Committee or other internal 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 loaner must provide Decontamination Units with a decontamination certificate, loan kit contents and reprocessing instructions so that the RIMD can be reprocessed safely using decontamination processes that comply with the most up to date version of the HSE Standards and Recommendation Practices for Central Decontamination Units (CDU).[5]

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

[5] **Note**: The 2014 HSE Document HSE Standards and Recommended Practices for CDUs. QPSD-D-003-2. V2.pub is currently being reviewed and an updated version is due to be published in 2024. Check HSE website for latest version.

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 support implementation 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 and reported.

2.6. All users are required to report risks, incidents and near misses to patients associated with the loaning and borrowing of RIMDs, when they occur/ are identified, in accordance with the hospital’s incident management policy and internal governance processes.

3. Explanation of Terms Used

ABBREVIATIONS:

- **ADR** European Agreement Concerning the International Carriage of Dangerous Goods by Road
- **CE** CE Mark that conforms to European Standards
- **CDU** Central Decontamination Unit
- **CJD** Creutzfeldt Jakob Disease
- **CSSD** Central Sterilising Supply Department
- **DDU** Dental Decontamination Unit
- **EDUs** Endoscope Decontamination Units
- **EN** European Standard
- **GS1** Global Standards
- **HSE** Health Service Executive
- **HIQA** Health Information Quality Authority
- **HPRA** Healthcare Products Regulatory Department
- **HSSU** Hospital Sterilising Services Unit
- **HPSC** Health Protection Surveillance Centre
- **ISO** International Standards Organisation
- **MDR** Medical Devices Regulation 2017/745
- **PCHCAI** Prevention and Control of Healthcare Associated Infections
- **RIMDs** Reusable Invasive Medical Devices
- **SLA** Service Level Agreement
- **UN** Certified by the United Nations
- **VHARMF** Voluntary Healthcare Agencies Risk Management Forum

The ADR Regulations -(2023)

The ADR 2023 (European Agreement Concerning the International Carriage of Dangerous Goods by Road) states:

2.2.62.1.1 "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."

2.2.62.1.5.3 "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
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 sterilisation 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 (MDR 2017/745).

Implantable Device
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 clinical intervention or surgery and intended to remain in place after the procedure for at least 30 days is also considered an implantable device. (MDR 2017/745)

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 3.

Medical Device

For the purpose of the Medical Device Regulation 2017/745

'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- 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 (MDR 2017/745).

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 Central Decontamination Units 2024[6] v3).

Supplier

Company who supplies RIMDs on loan or trial to a hospital

[6] [6] **Note**: The 2014 HSE Document https://www.hse.ie/eng/about/who/nqpsd/qps-improvement/hse-standards-and-recommended-practices-for-cdus-qpsd-d-003-2-v2-1.pdf is currently being reviewed and an updated version is due to be published in 2024. Check HSE website for latest version.

4. Key Principles

4.1. From a patient safety perspective, unnecessary loaning, borrowing and trialing of (RIMDs) should be strongly discouraged.

- All RIMD's must be reprocessed using the manufacturer guidelines in accordance with:
- ISO 17664-1:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices.
- ISO 17664-2:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices.

4.2. 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 that comply with the most up to date version of the HSE Standards and Recommended Practices for Central Decontamination Units (CDU)[7]

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

Risk	Application	Recommendation	*Examples* [4]
Critical	Items that enter sterile tissues/ sterile body areas or the vascular system	Requires sterilisation	*Surgical reusable invasive medical devices, biopsy forceps, laparoscopes, arthroscopes,* *Surgical dental RIMDs, e.g. forceps, elevators, luxators, scalers, surgical burs*
Semi-critical *(Not applicable to local dental decontamination services)*	Items in contact with mucous membranes or non-intact skin.	Sterilisation preferred but at a minimum, requires high level disinfection	*Flexible endoscopes,* *Specula,* *Respiratory therapy equipment*
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)	*Blood pressure cuffs, oximeters, ECG leads, denture fabrication equipment, apex locators, impression material dispensers*

4.3. All loaned, borrowed or trialed RIMD's must be accompanied by relevant manufacturers 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.

[7] **Note**: The 2014 HSE Document https://www.hse.ie/eng/about/who/nqpsd/qps-improvement/hse-standards-and-recommended-practices-for-cdus-qpsd-d-003-2-v2-1.pdf is currently being reviewed and an updated version is due to be published in 2024. Check HSE website for latest version.

4.4. Both loaning and borrowing hospitals and suppliers must have standard operating procedures in place to allow RIMDs to be manually or electronically tracked through:

4.4.1. The decontamination process in the loaning hospital / supplier prior to transportation to the borrowing hospital;

4.4.2. The decontamination process in the borrowing hospital prior to surgical/interventional procedure;

4.4.3. The decontamination process in the borrowing hospital following the surgical/interventional procedure prior to return to hospital of origin/supplier;

4.4.4. To the patient upon whom the RIMD(s) have been used, information must be stored and made available to relevant stakeholders in the event of a look back being required in accordance with local governance arrangements.

4.5. 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, CDU, CSSD, EDU) in accordance with local governance arrangements.

4.6. 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.

4.7. Hospitals and suppliers may consider implementing GS1 coding to provide unique identifiers for RIMD sets as outlined by the most up to date version of the HSE Standards and Recommended Practices for Central Decontamination Units (CDU)[8] 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.

4.8. 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 Healthcare Products Regulatory Authority as a sterilising entity and Transportation has been approved by the relevant ISO standard.

[8] **Note**: The 2014 HSE Document https://www.hse.ie/eng/about/who/nqpsd/qps-improvement/hse-standards-and-recommended-practices-for-cdus-qpsd-d-003-2-v2-1.pdf is currently being reviewed and an updated version is due to be published in 2024. Check HSE website for latest version.

5. Recommendations

5.1. Each Voluntary Healthcare Agencies Risk Management Forum member should draw up a hospital policy based on this framework, outlining the roles and responsibilities of CDU/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
- CDU/CSSD/HSSU Manager or equivalent
- Endoscopy Manager/ Dental Decontamination Unit Manager (if required).
- Relevant Theatre Clinical Nurse Manager/Senior staff nurse
- Relevant Surgical Team
- Suppliers/Companies

5.2. This framework relates to VHARMF members loaning and borrowing reusable medical devices from either VHARMF members or outside agencies. This document does not purport to provide advice to any outside agency as their insurance agreements will be significantly different.

5.3. All member agencies should have a vendor agreement approval process in place and within the agreement there should be a requirement placed on the agencies borrowing the device to appropriately insure when under their custody, care and control, this should extend, where required to the transportation to and from the agency's premises. This will then establish, in the event of damage/loss of the device, who is ultimately responsible for the loss and ultimately, it's repair/replacement. This is also applicable where member agencies are loaning devices to outside agencies that the appropriate vendor agreement is in place.

5.4. 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.

5.5. All loan/trial RIMDs must meet MDR 2017/745 Articles, 2, 5 and 20 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 (2019).

5.6. A loaning register must be held by lender to record details of patients on whom RIMDs have been to ensure full traceability. See sample in Appendix 3.

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

5.7.1. The hospital requirements with respect to the borrowing or trialing 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 of decontamination equipment and chemicals used, to relevant regulatory requirements.
- 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.
- 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.

5.8. This service level agreement is signed by the supplier and subject to annual or biannual review.

5.9. RIMD's borrowed between hospitals must be returned with a patient's MRN number on whom the RIMDs have been used and recorded on the loaning register to ensure full RIMD traceability (see sample in Appendix 3). The MRN number should be the only piece of patient information returned.

5.10. A record of the borrowed RIMDs used must be documented in the patient's healthcare record.

5.11. 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.

5.12. 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 Clinical Nurse Managers 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.

5.12.1. Any deviation from local policy should be based on risk assessment and 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. Roles and Responsibilities of the Supplier in the loaning/ trialing of 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 Healthcare Products Regulatory Authority requirements, Service Level Agreements with users and local governance arrangements.

6.2. Vendor authorisation must be provided to the supplier in writing by borrowing/trialing hospital into order for the Supplier to loan RIMDs to the hospital.

6.3. All loan/trial RIMDs must meet MDR 2017/745 Articles, 2, 5 and 20 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 trialed 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 trialing 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 with a minimum limit of indemnity of €6.5 million, Any One Claim basis.
- If the device is sourced directly from outside the EU, hospitals should ensure that they do not contract out of their potential subrogation rights against the supplier and the importance of same for non-EU suppliers.

- If the product is supplied from outside the EU, reference should be given to any additional obligations which the Hospital may assume when using the device. This will need to be checked by Procurement Manager / legal advisors in accordance with local governance arrangements.

6.7. All requests to loan/trial RIMD's must be made directly through relevant Theatre / Departmental Clinical Nurse Manager in the first instance.

6.8. **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: 2021;
- Any special requirements for assembly/ disassembly, lubrication or functional testing should be available.

6.9. **Training must be provided by the RIMD Supplier to Decontamination staff and users as required.**

6.10. **To facilitate full tracking of the decontamination process and traceability of patients on whom RIMDs have been used,** the **supplier should** maintain details of all records relating to the loaning/ trialing of RIMDs and make available in the event they are required for a look back exercise. This should include:

- Name and description of the RIMD set as defined by the supplier
- RIMD unique identification number/ asset number (e.g., GS1 code)
- Healthcare record number (MRN) of each and every patient that the RIMD was used on.
- Name and position of the person to whom the RIMD is lent to.
- Name of the Hospital and specific department/theatre where the RIMD is sent.
- Name and job title of the supplier representative who has loaned the RIMD.

6.11. 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.

6.12. 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 Trialing of RIMDS

7.1. Roles and responsibilities of Clinician/User in borrowing hospital

7.1.1. Clinicians/users have a responsibility and obligation to undertake the necessary control checks to protect patients, themselves and their organisations in accordance with the Healthcare Products Regulatory Authority requirements, Clinical Indemnity Scheme and Service Level Agreements approved within local governance arrangements.

7.1.2. Liaise with relevant Clinical Nurse Manager in charge prior to arranging to bring RIMDs into their theatre/department.

7.1.3. 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.

7.1.4. 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 HSSU/ CSSD/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 there is a vendor agreement approval process in place in accordance with local governance arrangements 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. If the device is sourced directly from outside the EU, hospitals should ensure that they do not contract out of their potential subrogation rights against the supplier and the importance of same for non-EU suppliers.

7.2.3. If the product is supplied from outside the EU, the Procurement Manager should check if there are any additional obligations which the Hospital may assume when using the device in accordance with local governance arrangements.

7.2.4. Ensure local governance arrangements are in place whereby RIMDs loaned or trialed that are outside those specified in existing Service Level Agreements have prior written executive management approval to proceed.

7.2.5. The hospital requirements with respect to the borrowing or trialing 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, training certificates, compliance of decontamination equipment and chemicals used to relevant regulatory requirements.
- 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.

7.2.6. 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 that the supplier delivers RIMDs to the Decontamination Unit allowing sufficient time to safely reprocess, in consultation with Theatre and HSSU/CSSD/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 advised in advance and contacted when it is delivered.

7.3.5. 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: 2021.
- Any special requirements for assembly/ disassembly, lubrication or functional testing should be available.

7.3.6. Inform the supplier/ loaning hospital of any discrepancies regarding kit /documentation completeness.

7.3.7. Check that the borrowed RIMD kit contents match the set list immediately prior to use.

7.3.8. Track the loan kit to the patient after the planned intervention.

7.3.9. Damaged or missing RIMDs must be inspected if required prior to use and inform Supplier / Loaning hospital of the discrepancy.

7.3.10. 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 Manager in the borrowing hospital following surgical intervention

7.4.1. 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.

7.4.2. RIMD borrowed must be returned with the MRN number of the patient on whom the RIMD was used. The MRN number should be the only piece of patient information returned.

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 representative 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: 2021;
- 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 of the Loaning hospital.

7.6.5. In the event that the borrowed RIMDs are being returned directly from the Decontamination Unit, ensure the loan kit is appropriately containerised for collection.

8. Management of Inter Hospital Loaning of RIMDS

8.3. Roles and responsibilities of relevant Clinical Nurse Manager in loaning hospital prior to loaning RIMD

8.3.1. 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.

8.3.2. 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: 2021.
- Any special requirements for assembly/ disassembly, lubrication or functional testing should be available.

8.3.3. Details of all RIMD's which are loaned to another Hospital should be captured (e.g., entered into a logbook (Appendix 3) or electronically scanned):

- Name and description of the RIMD set as defined in CDU/Theatre/ EDU/HSSU, CSSD.
- 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.

8.4. Roles and responsibilities of relevant Clinical Nurse Manager in loaning hospital following surgical intervention in the borrowing hospital

8.4.1. 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.

8.4.2. 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.

8.4.3. All returned RIMD's must be sent to the Decontamination Unit for cleaning, disinfecting and sterilising prior to return to normal circulation.

8.5. Transportation

8.5.1. All RIMDs must be decontaminated prior to transportation.

8.5.2. 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).

9. Bibliography

- ADR: These Regulations may be cited as the European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) (Amendment) Regulations 2023. SI No 197 of 2023 European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) (Amendment) Regulations 2023 Available at: SI No 197 of 2023 European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) (Amendment) Regulations 2023 - DETE (enterprise.gov.ie)
- Health Protection Surveillance Centre - Protocol for Reporting and Management of cases of Creutzfeldt Jakob Disease (CJD) and other Transmissible Spongiform Encephalopathies (TSEs) or of a person at increased risk of a TSE (2019) Available at: Reporting and Management CJD TSEs 2019.pdf (hpsc.ie)
- Health Information Quality Authority Standards for Safer Better Care 2012 https://www.hiqa.ie/sites/default/files/2017-01/Safer-Better-Healthcare-Guide.pdf
- Health Information Quality Authority National Standards for the prevention and control of healthcare-associated infections in acute healthcare services (2017) available at: National Standards for the prevention and control of healthcare-associated infections | HIQA
- Health Service Executive Standards and Recommended Practices for Central Decontamination Units 2024, V3.
- Health Service Executive Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities (2019) Available at: HSE Standards for Decontamination - HSE.ie
- Health Service Executive Guidance for the Application of Standards and Recommended Practices for Local Decontamination Units (LDUs) in Primary Care, Dental, Podiatry and GP Practice (2019) Available at: HSE Standards for Decontamination - HSE.ie[9]
- Health Service Executive Medical Devices/Equipment Management Policy 2019 Available at OQR030v4 Medical Device Equipment Management Policy (hse.ie)
  Health Service Executive and Healthcare Products Regulatory Authority Medical Device Regulation (2021) Available at: Medical Device Regulation and CE Marking - Corporate (hse.ie)
  Health Protection Surveillance Centre –Point Prevalence Survey of Hospital Acquired Infections and Antimicrobial Use in European Acute Care Hospitals May 2017 – Republic of Ireland National Report; Dec 2018. Available at: PPS 2017 National Report_FINAL_191218.pdf (hpsc.ie)
- Healthcare Products Regulatory Authority (2021) Guide to classification of Medical Devices Available at: Qualification and classification of medical devices (hpra.ie)

[9] **Note**: The 2014 HSE Document HSE Standards and Recommended Practices for CDUs. QPSD-D-003-2. V2.pub is currently being reviewed and an updated version is due to be published in 2024. Check HSE website for latest version.

- ISO 17664-1:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
- ISO 17664-2:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
- Medical Device Regulation (EU) 2017/745 Available at:-Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex (europa.eu)

For further information on decontamination please see HSE resources:

HSE Standards for Decontamination - HSE.ie

10. Appendix One - Membership of Working Group that produced this Framework.

Membership of the Working Group who updated an original document behalf of the VHARMF in 2014 and reviewed in 2018 and 2021:		
NAME	**ORGANISATION**	**POSITION**
Ms. Caroline Conneely	Children's University Hospital Temple Street	CDU Manager/ Decontamination Advisor
Ms. Monica Griffin	St. James's Hospital	Theatre Manager CNM3
Mr. Andrew Smith	St. James's Hospital	HSSU Manager
Ms. Mary Connolly	Aon Healthcare	Head of Healthcare Risk Management

Reviewed in 2024 by the following in consultation with all VHARMF member agencies:

NAME	**ORGANISATION**	**POSITION**
Ms. Caroline Conneely	Health Service Executive, Quality and Patient Safety Directorate	National Decontamination Advisor and QI Facilitator
Ms. Monica Griffin	CHI @ Crumlin	Assistant Director of Nursing
Mr. Andrew Smith	St. James's Hospital	HSSU Manager
Ms. Mary Connolly	Aon Healthcare	Director of Healthcare Risk Management

11. Appendix Two - Sample 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 ☐
2. Automated Washer/Disinfection ☐
3. High Level Disinfection ☐
4. Sterilisation ☐

PRINT Name of person releasing items: _____

Position: _____ **Department:** _____

Date: _____ **Signature:** _____

Voluntary Healthcare Agencies Risk Management Forum

12. Appendix Three - Sample 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 NUMBER:

_____

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):

_____

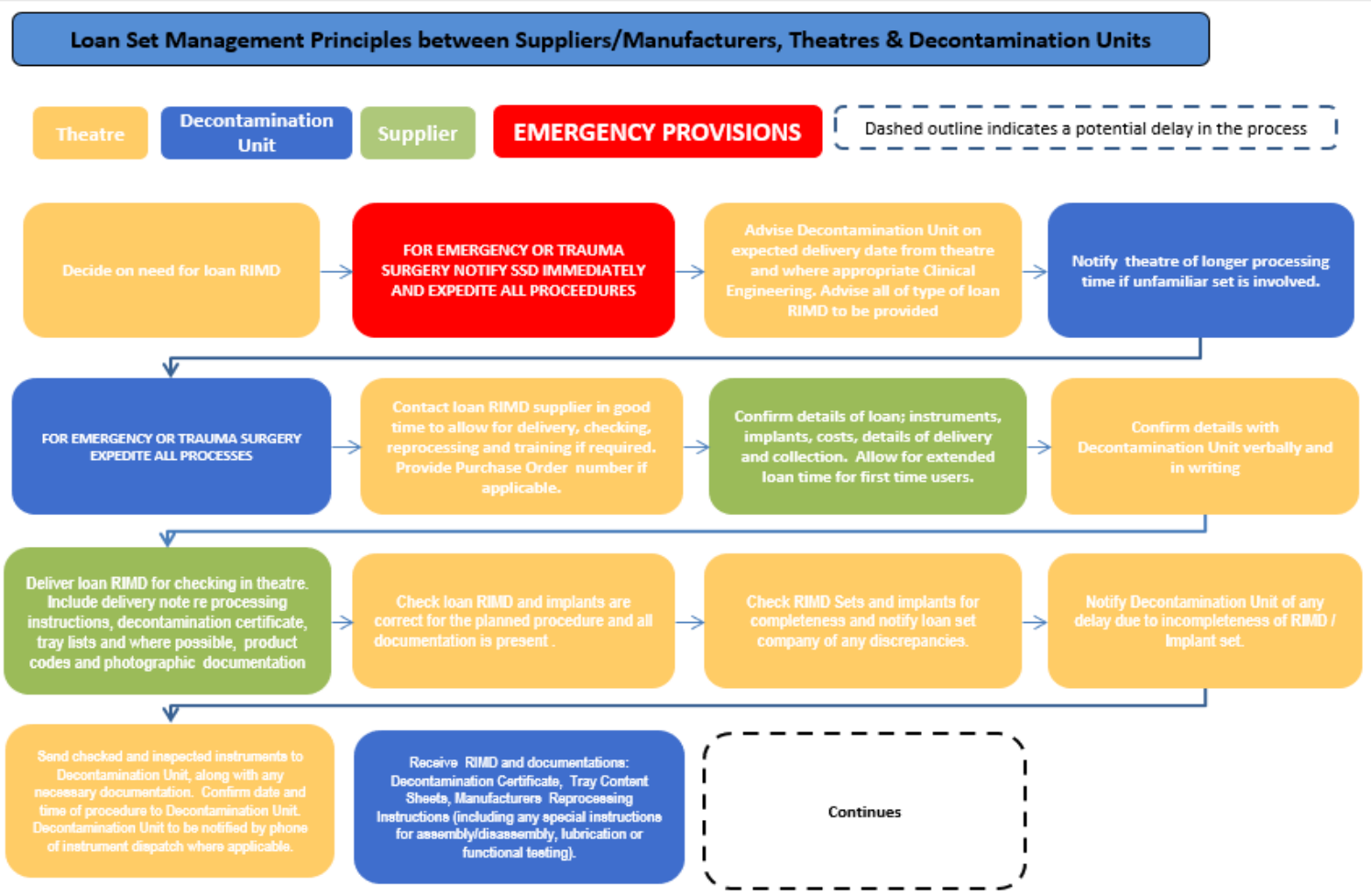
_____

13. Appendix Four - 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, disinfection, and sterilisation Instructions**		**Is Decontamination Certificate Attached?** **RIMD Set Check Lists Received?**	
RIMD Check Complete?		**Information and RIMD Contents Correct?**	
Are cleaning instructions compatible with current decontamination methods used in 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			

Date Re Processed in CDU			
Decontamination Cert			
Signature		**Date**	

14. Appendix Five - Loan Set Management Principles between Suppliers/ Manufacturers, Theatres & Decontamination Units




Establish RIMD/Implant set on the IT System and generate tracking labels for theatre use.
Process RIMD/Implant sets according to local procedures.
Dispatch loan RIMD/Implant and documentation to the theatre.
Inspect RIMD/Implant to ensure packaging integrity and assure sterility.
Check that all instruments are present, in the correct tray and in the correct tray location.
Operation performed.
Track RIMD/ Implant details to patient.
Check that all instruments are present., in the correct tray and in the correct tray location before returning to the Decontamination Unit. Document the number and type of implants used on the tray list where appropriate.
Complete supplier's usage form and reconfirm purchase order if necessary.
Return RIMDs to Decontamination Unit for reprocessing.
Reprocess RIMD according to local procedures. Ensure that trays are free of locally-fixed tape and/or labels. (If sets to be collected from Decontamination Unit, ensure they are appropriately containerised/packaged and addressed.
Return RIMD to theatre within the agreed time scale for collection by supplier. Theatres must arrange return of RIMD to loaning Hospital. Decontamination certificates should accompany sets.
Ensure loan RIMD are appropriately containerised/packaged and addressed for collection by supplier at the agreed time for return to the loaning hospital.
Collect RIMD sets from the theatre.

15. Appendix Six - Implantable Devices

While the focus of this document pertains to the loaning and borrowing of Reusable Invasive Medical Devices, it is recognised that Implantable Devices are also borrowed with intent to be used in combination with RIMD's. These implants will also need to be controlled to ensure they are sterile and fit for purpose.

Definition

Under the EU Medical Device Regulation (MDR) 2017/745 an 'Implantable device' is any device, including those that are partially or wholly absorbed, which is intended:

- To be totally introduced into the human body, or to replace an epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure.
- Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device".
- Implants may be supplied sterile or non-sterile and are all labelled as single use.

The term 'single-use device' means a device that is intended to be used on one individual during a single procedure (MDR 2017/745).

To ensure patient safety, implants that are intended to be used in combination with RIMD that are loaned, borrowed or on trial for a surgical procedure must be considered as part of the loan, borrowing or trial consignment.

Management of implants that are intended to be used alone or in combination with RIMD's that are on loan, borrowed or on trial must meet the following criteria

Pre-packed sterilised implants from original manufacturer

- If the manufacturer has supplied a pre-packed sterile single use implant with a tracking label, lot number and expiry date, these implants do not need to be reprocessed in the Decontamination facility prior to use, if the following criteria are met:
  - I. The original manufacturer packaging is intact and is not damaged in any way (the implant remains sterile as intended),
  - II. The implant packaging has not been opened,
  - III. The implant has been stored correctly and is used in accordance with manufacturer instructions,
  - IV. The implant has not reached its expiry date.
  - V. The implant is CE marked.
  - VI. The implant contains a tracking label to allow the implant to be either electronically or manually recorded in the patient's healthcare records/ implant register/theatre notes etc.

Implants processed by CDU/HSSD/CSSD

- Non-sterile single use implants that are supplied by the manufacturer may be decanted into an implant tray or caddy to allow ease of access during a surgical procedure or may be presented individually before processing in a decontamination facility.
- If such implants are borrowed and intended to be used in combination with RIMD's that are loaned borrowed or on trial, or if they are individually borrowed, they must be reprocessed in the borrowing institution with the RIMD prior to use ensuring they are fully traceable through the decontamination process even if they have been presented as sterile by the loaning hospital.

  Implant tray/ caddy content list should be provided by the supplier or the loaning hospital (this should be a list of actual contents per tray for example, implant size/ number of implants and not simply a list of implants in the tray/caddy. Tray/caddy specification shall include implant codes where available and photographic evidence where possible).

- Manufacturer's reprocessing instructions must be supplied in accordance with ENISO:17664: 2017.
- A record of the borrowed implant that has been used must be documented in the patient's healthcare record.
- Non-sterile single use implants intended to be used in combination with the RIMD that are loaned borrowed or on trial must be accompanied by relevant reprocessing instructions, list of contents and decontamination certificate.

16. Appendix Seven - HSE Advisory Notice: Surgical Implants-Relating to the reprocessing of surgical implants under the Medical Device Regulation (EU) 2017/745 (Article 17 – Single-use devices and their reprocessing).

Géaroibríochtaí
Aonad 4A, Áras Dargan, An Ceantar Theas, An Bóthar Míleata Cill Mhaighneann, Baile Átha Cliath 8

Acute Operations
Unit 4A, The Dargan Building, Heuston South Quarter, Military Road, Kilmainham, Dublin 8

☎: 01 79 59937 : ncagl.hospitals@hse.ie

Date:	28th September 2021
To:	Hospital Group CEO's
Cc:	
From:	Dr Vida Hamilton, NCAGL Acute Operations
RE:	Advisory Notice: Surgical Implants-Relating to the reprocessing of surgical implants under the Medical Device Regulation (EU) 2017/745 (Article 17 – Single-use devices and their reprocessing).

Dear Colleagues,

The HSE have become aware that there may be some confusion relating to the repeated reprocessing of single use non-sterile and sterile implants under the Medical Device Regulation (MDR) 2017/745 which came into force on May 26th 2021.

The MDR- Article 17 States:

- The term 'single-use device' means a device that is intended to be used on one individual during a single procedure (MDR 2017/745).
- The term 'reprocessing' means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilization and related procedures, as well as testing and restoring the technical and functional safety of the used device.
- Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with Article 17 of the MDR 2017/745.

Implants

"The (MDR) 2017/745 states that an 'Implantable device' is any device, including those that are partially or wholly absorbed, which is intended:

- *To be totally introduced into the human body, or to replace an epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure.*

- *Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device[2].*

Presentation of Implants

- Implants may be supplied sterile or non-sterile and are all labelled as **single use**. *The term 'single-use device' means a device that is intended to be used on one individual during a single procedure (MDR 2017/745).*

Question

Can we reprocess single use non-sterile implants?

Answer

1. In practice, single use implants which are supplied non-sterile are frequently decanted into an implant tray or caddy to allow ease of access during a surgical procedure. **Non- sterile implants must be processed/ decontaminated (cleaned, disinfected and sterilized) prior to use in accordance with the manufacturer's decontamination instructions.** These instructions are detailed in the "Instructions for Use" (IFU) document which comes with the non-sterile implant.

2. If a non-sterile single use implant, which was processed prior to a surgical procedure, has not been "used on one individual during a single procedure" the manufacturer **may** allow, **in some cases**, for the single use implant to be repeatedly reprocessed and **only** in accordance with the implant manufacturer's IFU.

3. The Reprocessor (Decontamination Unit or Outsourced Decontamination Service) and Theatre, must ensure that, if the manufacturer allows repeated reprocessing of the single use implant, that has not been used on "one individual during a single procedure", that this is clearly stated within the IFU document that came with the implant. The IFU must include reprocessing instructions that are compatible with the Decontamination Units reprocessing facilities. **If the implant has been used on or in contact with the patient, the implant must not be reprocessed.**

4. If the manufacturer states that the single- use implant may be reprocessed, if it has not been used on or in the patient, advice should be sought from the manufacturer to establish if there is a limit on the number of times the implant may be reprocessed before it must be discarded. If the manufacturer has set a limit on the number of times the implant can be reprocessed, if not used on a patient, a tracking system must be in place to trace the implant and monitor the number of times it has been reprocessed.

Question

Can we reprocess single use implants that are supplied already sterile from the manufacturer?

Answer

1. **Single use implants that are supplied already sterile from the manufacturer must be managed in accordance with the manufacturer's instructions.** These

Instructions are detailed in the "Instructions for Use" (IFU) document which comes with the sterile implant. If the single use implant is supplied by the manufacturer already sterile (often using radiation or ethylene oxide sterilization processes), most manufacturers will **not** allow the device to be reprocessed **even** if it has been "opened and not used".

2. Occasionally a manufacturer may allow for the single use implant, that was originally supplied sterile and not used on "one individual during a single procedure", to be reprocessed. However, if the manufacturer allows for repeated reprocessing of a single use implant that was originally supplied sterile and not used, the Theatre and the Reprocessor must ensure that this is clearly stated within the implant IFU document and includes reprocessing instructions that are compatible with the Decontamination Unit's reprocessing facilities. **If the implant has been used on or in the patient the implant must not be reprocessed.**

3. If the manufacturer states that the single- use implant, that was originally supplied sterile, may be re processed, if it has not been used on or in the patient, advice should be sought from the manufacturer, to establish if there is a limit on the number of times the implant may be reprocessed before it must be discarded. If the manufacturer has set a limit on the number of times the implant can be reprocessed, a tracking system must be in place to trace the implant and monitor the number of times it has been reprocessed.

Summary

If the original manufacturer has deemed that an implant can be further reprocessed, if the implant was not used on or in the patient, the information for the User (IFU) must be supplied by the manufacturer of that implant and must include:

- The manufacturer's instructions for implant use.
- Reprocessing instructions.
- Specific guidance relating to when the device should not be reprocessed.

In all cases, the implant must only be handled and further processed **in accordance with the manufacturer's instructions for use** and if there is any ambiguity in this regard, written advice / clarification should be sought directly from the original device manufacturer.

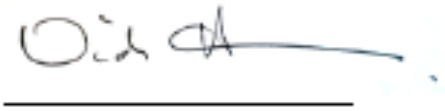
NOTE: It is critical that the Theatre and the Reprocessor (Decontamination Unit or outsourced Decontamination Service) are aware of the manufacturer instructions for all implants that are used or processed by their institution as these instructions may vary between manufacturers and may change over time, particularly in light of the new Medical Device Regulation (MDR).

Access the Medical Device Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

End

I would be grateful if you could bring this notice to the attention of relevant personnel such as Clinical Directors/General Manager / Theatre Manager/ Decontamination Lead/ Infection Prevention Control / Risk Manager/ Medical Device Equipment Management Committee/ Vigilance Officer.

Regards



Dr. Vida Hamilton
National Clinical Advisor and Group Lead – Acute Hospitals

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