Loan Set Management and Individual Medical Devices Principles Between Suppliers/Manufacturers, Theatre Departments and Decontamination Units

Introduction

These guidelines are intended to assist all healthcare personnel in managing loan sets and individual reusable medical devices and provide a process whereby each loan event may be managed effectively, efficiently and ensure continued patient safety. It will ensure that the medical devices are in the right place at the right time and in the right conditions for use.

Healthcare is devolved across four nations and therefore, each nation must follow its own relevant guidance.

It is recognised that there are many variations within organisations in relation to the responsibility of the management of loan sets/medical devices.

- **The Theatre Department's (TD) responsibility to manage the process:** The Theatre Department will identify the loan sets/medical devices required and notify procurement if appropriate and the Decontamination Unit (DU) of what is required, when it will be delivered and the date and time of the procedure.
- **Decontamination Unit responsibility:** The clinical team will advise the DU of what loan medical devices are required and the procedure time and date. The DU will manage the purchase order and delivery and processing of the loan sets/medical devices to meet the clinical teams' timescales.

The DU should either be certified to ISO 13485 (2016) Medical Devices - Quality Management Systems - Requirements for regulatory purposes or operate a Quality Management System (QMS) which is externally verified. Decontamination processes will be detailed within the DU QMS. All loan sets must be tracked through the decontamination process including documented in patients notes. This must include any implants. Allowance for training for both clinical teams and DU must be facilitated.

It is recognised that many healthcare organisations have agreements in place whereby loan sets/devices move between sites. In all the scenarios above, the principles described in this document should be followed and used as a best practice guide.

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It should be considered whether the DU is on the hospital site where the medical devices are to be used or off-site, as time will need to be factored in for the transportation of the devices to the DU using scheduled transportation. This will be determined by a local policy or contractual agreement between the service provider and customer.

The steps outlined below (Appendix 1; tables 1and 2) provide a description of the entire process for loan set management.

The intention of this document is to demonstrate the chain of actions required to achieve a timely, effective and safe process. It is essential that the loan process is seen from a holistic view, as if one party fails to deliver, the consequences will impact patient care.

The DU will have a capacity limit, and loan sets will occupy a significant proportion of capacity, as most loan sets have multiple layers of devices. If several clinical users require loan sets at the same time, this may impact turnaround times. In addition, fast-tracking sets will have a detrimental effect on the overall efficiency of the DU.

Any user of a device needs to understand how the manufacturer intends the device/equipment to be used and how it normally operates, to be able to use it effectively and safely. (Managing Medical Devices, MHRA 2021 sect 6.2.)

Following a survey issued by the IDSc to its members in 2024, the following areas were identified as potential risks related to the management of loan sets:

- Some loan sets are supplied that are excessively heavy and the design of the trays can cause damage to the tray wraps. The DU unit may decant the devices into containers or din baskets for the decontamination process. If this occurs, then the process must be validated.

- Information for User's, if Instructions for Use (IFU) documentation is incomplete or does not comply with United Kingdom (UK) guidance. There for before use contact the suppliers of the loan kit to ensure IFU compliance with UK requirements.

- Failure to track implants supplied in loan sets to individual patients has been inconsistent, thereby potentially compromising patient safety, implant traceability, and regulatory compliance.

Set integrity needs to be maintained to minimise instrument migration and enable traceability to the patient. This extends to the control of individual instruments and

implants within loaned sets, to audit their removal and replacement. Suppliers of the loan sets should be contacted regarding the systems they have in place for the management of traceability of their implants.

When supplying unsterile implants, suppliers should explain the process to ensure that implant lot and serial number details can be added to the patient intraoperative record/documentation, to ensure traceability and tracking of devices. If there are any concerns, a full risk assessment should be completed.

In Scotland the Scottish Executive issued NHS HDL (2027) 4 - DECONTAMINATION – MIGRATION TO SINGLE-USE PRE-STERILISED INDIVIDUALLY WRAPPED SMALL addressing and the move to presterile implants. This gave a deadline of 31st December 2007 for all orthopaedic units to have changed over to using pre-packed sterile single-use implants.

Provision of sterile loan trays delivered to theatre department and then sent to DU post procedure for decontamination. These should be checked by theatre personnel and then sent to DU for a complete full decontamination process.
In cases of clinical emergency, risk assess and follow local policy.

Appendix 1

Loan Set Management Principles Between Suppliers/Manufacturers, Theatre Departments and Decontamination Units

Sample Recommended Timetables for Notice, Receipt of Loan Set/Medical Devices

Table 1: Known loan sets/devices

Loan sets/medical devices familiar to the decontamination unit			
Day of Clinical Use	Notice of DU of loan set/medical devices Requirements with IFUs	Loan set/medical devices to be sent to the DU	Available for collection by the Medical Supplier
Monday	Wednesday 1 p.m.	Friday 8 am	Wednesday
Tuesday	Thursday 1 pm	Friday 1 pm	Thursday
Wednesday	Friday 1 pm	Monday 1 pm	Friday
Thursday	Monday 1 pm	Tuesday 1 pm	Friday
Friday	Tuesday 1 pm	Wednesday 1 pm	Monday
Saturday	Wednesday 1 pm	Thursday 1 pm	Tuesday
Sunday	Wednesday 1 pm	Thursday 1 pm	Wednesday

Table 2: New loan sets/medical devices

Loan sets/medical devices to be processed for the first time on a specific site			
Day of Clinical Use	Notice to the DU of the loan set/medical device. Requirements with IFUs	Loan set/medical device to be sent to the DU	Available for collection by the Medical Supplier
Monday	Wednesday 1 p.m.	Thursday 8 am	Wednesday
Tuesday	Thursday 1 pm	Thursday 1 pm	Thursday
Wednesday	Friday 1 pm	Friday 1 pm	Friday
Thursday	Monday 1 pm	Monday 1 pm	Friday
Friday	Tuesday 1 pm	Tuesday 1 pm	Monday
Saturday	Wednesday 1 pm	Wednesday 1 pm	Tuesday
Sunday	Wednesday 1 pm	Wednesday 1 pm	Wednesday

*** The DU should be notified by theatre department of all planned loan set/medical device requirements for weekend and Monday use by Wednesday, 1 p.m. at the latest. ***

Post procedure, the loan sets/medical devices must be returned to the DU on the next available transport/collection. The DU will undertake the full decontamination process and provide a decontamination certificate prior to the collection of the loan sets/medical devices by the manufacturer. This should be a minimum of 23 hours post use unless local policy or contracts determine a different time period.

To prioritise sets/medical devices being returned to the manufacturer could inadvertently cause delays in the normal turnaround times for other sets/medical devices.

Process for Decontamination Units (DU)

1. Planning

To allow adequate time for processing prior to use by the TD, it is important that the loan set/medical devices and the required information are supplied to the DU according to the timescale set out below.

Where the DU is notified that the theatre department intends to use a loan set/medical device that the DU is unfamiliar with, then they will notify the TD, within 24 hours, to arrange a longer process time to allow for training and processing.

In the case of emergency or trauma surgery, the DU must be advised and identify the loan sets as a fast track to meet the timescales of the patient procedure.

2. Documentation including traceability of the process.

The DU will generate unique identifiers (barcodes) for each loan set/medical device and enter the information onto the departmental information system (track and trace). This will ensure traceability of the sets through the decontamination process and provide information to the clinical user to enter into the patients notes.

The following documents must be supplied with the loan set, this will apply to procurement, theatre department and the DU.

Tray Form: fully completed by theatre department.

Valid Decontamination Certificate: from the loan set supplier.

Tray Content Sheet: (this should be a list of the actual contents per tray and not simply a list of medical devices in the set. (digital images of the tray and contents are acceptable). This will include product codes.

NOTE. The devices should be removed from the graphic tray prior to being processed in the automated washer disinfector. Multi-layered sets must be separated to ensure that the devices can be cleaned and disinfected effectively. If there are any concerns, then internal validation using a residue soil test may be required.

Manufacturer's Reprocessing Instructions in accordance with EN ISO 17664-1:(2021), any special requirements for assembly/disassembly, lubrication, or functional testing should be provided.

Indemnity Certificate: from the loan set provider.

All devices on loan from manufacturers should be subject to a written agreement which defines the device management requirements, responsibilities and liabilities, including decontamination if applicable. See the NHS Master Indemnity Agreement. Delivery receipt and pre-use procedures for loan devices should be the same as those for

purchased devices unless otherwise specified in this written agreement *(Management of medical devices, MHRA 2021, Sect 5.2.2)*.

3. General

If the DU finds any discrepancies in the loan set, such as damaged or missing devices, they will quarantine the set in an unprocessed condition for the clinical users or loan set company to inspect and the clinical users advised immediately the error is identified.

It must be ensured that there is no migration of medical devices from the sets in which they were received from the supplier.

Process instrument sets according to local decontamination procedures, which should be compliant with HTM 01-01Part A (2016) guidelines.

Post sterilisation, the loan sets and devices must be allowed to cool to ambient temperature to reduce the risk of 'wet wraps' and therefore the need for the decontamination process to be repeated in its entirety.

The loan sets are dispatched using the appropriate transportation system, ensuring that sets are not stacked on top of each other, to assist in the prevention of damaged wraps.

When the procedure has been completed, the loan sets/medical devices must be returned to the DU and processed through the decontamination cycle. All trays must be free from any locally fixed tape or labels.

The decontaminated sets must be returned to the supplier in accordance with local policy, with an appropriate decontamination certificate.

Appendix 2

Loan Set/Medical Device Principles Between Suppliers/Manufacturers, Theatre Departments (TD) and Decontamination Units (DU)

Loan Set/Medical Device Order to Payment Example Checklist

(Theatre Department)

This example checklist should be tailored for individual circumstances, to include the end-to-end activities from ordering to payment regarding loan sets/medical devices used in the TD. In the example given, the TD has a named individual/team in theatres responsible for the request of a loan set/medical device. This should be substituted with any local theatre terminology.

	Process Description	Responsibility	
1.	Stores/procurement receives loan kit requirements from the surgical division/theatres.	Theatre department	☐
2.	Stores/procurement creates a requisition in line with local policy and procedures.	Stores procurement/theatre department	☐
3.	The responsible person in theatres contacts the supplier and orders the loan kit with the requisition number given by Stores/Procurement.	Theatre department	☐
4.	Suppliers send out the loan set/medical devices with the purchase order number.	Loan set/medical device suppliers	☐
5.	The responsible person in the TD checks the contents of each loan set/medical device before use and updates the check sheet.	TD	☐

6.	The responsible person in the TD once checked sends each loan set/medical device to DU.	TD	☐
7.	After the procedure, the responsible person in the TD check the contents of each loan set/medical device against the check sheet before returning the loan set/medical device to DU.	TD	☐
8.	Any loan sets/medical devices that have not been unpacked do not need reprocessing.	TD	☐
9.	Receipting and financial procedures should be undertaken in compliance with your organisational policies.	TD	☐

Appendix 3

Loan Set Management Principles Between Suppliers/Manufacturers, Theatre Departments and Decontamination Units

Process for Theatre Departments

1. The TD receives notification of surgery, and a determines whether a loan set/medical device is required.
2. In the case of emergency or trauma surgery, the theatre will advise the DU immediately when the need for the use of a loan set/medical device is recognised. Both the theatre department and the DU will use their best endeavours to expedite the ordering, supply, checking and processing of the loan set/medical devices to minimise continuing patient risk of delay and cancellation. In such circumstances, the loan set/medical devices will be regarded as a 'fast track' item, i.e. will take priority over elective loan sets/medical devices which may be in process. Any delays in processing will be communicated to the customer.
3. Elective surgery loan sets/medical devices should be booked well in advance from the medical supplier. The TD should advise the DU as soon as it has done so and confirm the expected delivery date from the TD to the DU. The TD should provide the DU with information on loan sets/medical devices that are unfamiliar to them. The DU will maintain and make available a list of loan instrument sets/medical devices with which it is familiar. For sample timescales (see Tables 1 and 2).
4. The TD contacts the loan set/medical device supplier to arrange delivery to a specified location(s) in good time to allow for checking, reprocessing and training if required. A purchase order should be supplied at the time to cover the consumables used and/or hire charges if applicable. The TD should be aware that additional time will be required to facilitate training for both theatres and DU personnel if an unfamiliar loan set/medical device is involved.
5. The TD confirms loan set/medical device details with the DU both verbally and in writing.

NOTES:

Should also allow for additional time that may be required for loan sets/medical devices that are unfamiliar to the DU there may be special processing requirements (such as a process compatibility review) or training that needs to be arranged, as well as the installation of tray information into the tracking and traceability system.

6. On receipt at the TD, loan sets/medical devices and implants should be checked for completeness and any discrepancies should be notified to the loan set/medical devices supplier immediately.

7. The DU should also be informed of any potential delay.

8. The TD will send the checked and inspected loan sets/medical devices to the DU within the agreed timescale, and in accordance with the hospital's procedures. Theatre personnel should confirm the date and time of the operation and send all necessary documentation as defined in this guidance. The DU must be notified of the loan sets'/medical devices' impending arrival via a telephone call.

9. The TD inspects loan sets/medical devices to ensure the process indicator has changed according to local policy. Check the packaging is intact, dry and sterility has not been compromised.

10. The TD checks immediately prior to the procedure to ensure all loan sets/medical devices are present and in the correct tray location before use.

11. Procedure performed.

12. The TD takes responsibility for tracking tray details to the patient notes, which includes implants in accordance with national and local policy.

13. The TD checks to ensure all loan instruments/medical devices are present and in the correct tray location prior to returning to the DU.

14. The TD completes the usage form enclosed with the loan set/medical devices supplier's documentation and reconfirms the purchase order if necessary.

15. The TD returns loan sets/medical devices to DU for reprocessing as per local procedures.

16. The TD ensures loan sets/medical devices are appropriately containerised/packaged and addressed for collection by the supplier at the agreed time.

Appendix 4

Loan Set/Management Principles Between Suppliers/Manufacturers, Theatre Departments and Decontamination Units

Checklist for Theatre Departments

	Process Description	
1.	Decide on the need for a loan set/medical device.	☐
2.	**FOR EMERGENCY OR TRAUMA SURGERY, NOTIFY DU IMMEDIATELY AND EXPEDITE ALL PROCESSES**	☐
3.	Advise DU on the expected delivery date from the TD, along with information on the type of loan set/medical device to be provided.	☐
4.	Contact the loan set/medical device supplier in good time to allow for delivery, checking, reprocessing and training if required. Provide the Purchase Order Number.	☐
5.	Confirm details of the loan sets/medical devices with dates of estimated arrival and procedure date to DU both verbally and in writing.	☐
6.	Check instrument sets/medical devices and implants for completeness and notify the loan set/medical device company of any discrepancies.	☐
7.	Notify DU of any delay due to the incompleteness of loan sets/medical devices.	☐
8.	Notify the DU and send checked and inspected loan sets /medical devices with the relevant documentation. Confirm the date and time of the procedure to DU.	☐
9.	Inspect loan sets/medical devices to ensure the process indicator has changed according to local policy. Check the packaging is intact, dry and that sterility has not been compromised.	☐

	Process Description	
10.	Check that all the loan sets have been received and medical devices are in the correct tray and location.	☐
11.	Procedure performed	☐
12.	After the procedure, check that all loan sets are present and that medical devices are in the correct tray and location.	☐
13.	Complete the supplier's usage form, e.g. implants and reconfirm the purchase order if necessary.	☐
14.	Return loan sets/medical devices to DU for reprocessing.	☐
15.	Ensure loan sets/medical devices are appropriately containerised/packaged and addressed for collection by the supplier at the agreed time.	☐

Appendix 5

Loan Set Management Principles Between Suppliers/Manufacturers, Theatre Departments and Decontamination Units

Process for Decontamination Units

1. To allow adequate time for processing prior to use by the TD, it is important that the loan set and the required information is supplied to the DU according to the timescale set out below. Where the DU is notified that the TD intends to use a loan set that the DU is unfamiliar with then the DU will notify theatres, within 24 hours, to arrange a longer process time to allow for training and processing. [For sample timescales, see table 2].

2. **In the case of emergency or trauma surgery, the DU will have been advised and should expedite all processes to minimise continuing patient risk.**

3. If the DU finds any discrepancies in the loan set, such as damaged or missing instruments, the DU will quarantine the set in an unprocessed condition for the theatre department or loan set company to inspect. The DU should alert the TD of the reason for the quarantine within 30 minutes of the discrepancies being discovered.

4. The DU receives the instrument sets and documentation necessary for reprocessing: Loan Tray Form: fully completed by theatre department.
   Valid Decontamination Certificate: from the loan set supplier.
   Tray Content Sheet (this should be a list of the 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 ISO 17664-1:2021 any special requirements for assembly/disassembly, lubrication or functional testing should be provided.

5. The DU establishes tray(s) on the IT system and generates tracking labels for the TD use to allow tracking back to the decontamination process.

6. Process instrument sets according to local procedures.

7. The DU dispatches loan sets and documentation (tray content sheet & loan tray form) to the TD.

8. The DU reprocesses sets for return to theatre for collection by supplier. Trays should be free of locally fixed tape or labels. (If trays are to be collected from the DU, then the DU ensures that sets are appropriately containerised/packaged and addressed for collection by supplier at the agreed time.) The DU should ensure that migration of instruments does not take place between trays/sets while in their care.

9. The DU returns sets to the TD within the agreed timescale in readiness for collection by the supplier. Sets should be accompanied by decontamination certificates.

Appendix 6

Loan Set/Medical Devices Principles Between Suppliers/Manufacturers, Theatre Departments and Decontamination Units

Checklist for Decontamination Units Process Description

	Process Description	
1.	Receive loan sets/ medical devices and documentation: Loan Tray Form, Decontamination Certificate, Tray Content Sheets, Manufacturer's Reprocessing Instructions (including any special instructions for assembly/disassembly, lubrication, or functional testing), Indemnity certificate.	☐
2.	Confirm that the manufacturer's Instructions for Use (IFUs) are compatible with the decontamination process that can be provided. Highlight immediately any issues and do not process them against the manufacturer's IFUs.	☐
3.	Notify the TD if training is required before processing. Quarantine any sets/medical devices when a discrepancy is identified, e.g. missing or damaged devices. Inform the TD immediately and await instructions before proceeding.	☐
4.	Emergency or trauma surgery loan sets/medical devices must be fast-tracked.	☐
5.	Enter the data into the DU information system (track and trace) according to local policy and generate tracking labels to ensure traceability of the devices through the decontamination process and to the patient.	☐
6.	Process Loan sets/medical devices according to local procedures.	☐
7.	Dispatch loan sets/medical devices and documentation to the TD.	☐

8.	All locally attached IDs, tape and labels must be removed from the loan sets/medical devices before returning to the supplier.	☐
9.	A decontamination certificate must be completed detailing the decontamination process carried out in the DU.	☐
10.	Return sets to the TD/supplier within the agreed timescale.	☐

Appendix 7

Loan Set Management Principles Between Suppliers/Manufacturers, Theatre Department and Decontamination Unit

Process for Manufacturer/Supplier

1. The loan supplier confirms details of loan sets/medical devices, implants, costs, dates of delivery and collection. Loan suppliers/manufacturers should be aware that first-time users will require extended loan times to allow for training in TD and DU.
2. Loan supplier delivers loan sets/medical devices and implants to a specified location(s) for initial check by theatre or according to local policy. All deliveries should be accompanied by a delivery note, manufacturer's instructions for use (IFU's), decontamination certificate, and detailed medical device lists, by set and in a logical layout. Include product codes and photographic documentation where possible.

NOTES:
The supplier should also ensure that the weight of any individual tray does not present a manual handling risk, Health and Safety Executive (HSE 2020) "Manual Handling at Work: A Brief Guide".

Reprocessing instructions should conform to International Organisation for Standardisation (ISO)17664-1:2021 and should include disassembly diagrams where applicable.

- Loan set and medical device suppliers should implement a robust track-and-trace system for all reusable medical devices. This will enable accurate tracking of each device throughout its entire lifecycle—from delivery to final decontamination or disposal—and will support healthcare providers in identifying and tracing any patients who may have been exposed to a specific device in the event of a variant Creutzfeldt-Jakob disease (vCJD) diagnosis in a prior patient or a product recall.
- Loan set/medical device suppliers should ensure that migration of instruments does not take place between loan sets. All medical devices should be linked to trays with serial numbers.

3. Supplier collects loan sets/medical devices from the designated TD or pre-arranged point.

Appendix 8

Loan Set Management Principles between Suppliers/Manufacturers, Theatre Departments and Decontamination Units

Checklist for loan set/medical device suppliers

	Process Description	
1.	Confirm details of loan: sets/medical devices, implants, costs, dates of delivery and collection. Allow for extended loan time for first-time users.	☐
2.	Deliver the loan set/medical devices for checking by the theatre personnel. Include a delivery note, IFU, decontamination certificate, tray lists and, where possible, product codes and photographic documentation.	☐
3.	Collect sets from the designated TD or a pre-arranged location.	☐

Authors

AfPP

Association for Perioperative Practice, Daisy Ayris House, 41 Freemans Way, Harrogate,

North Yorkshire, HG1 1DH

Tel: +44 (0)1423 508079, Fax: +44 (0)1423 531613,

Email: www.afpp.org.uk/contact-us/contact-us , web: www.afpp.org.uk

IDSc

Institute of Decontamination Sciences, Victory House, 400 Pavilion Drive,

Northampton, NN4 7PA

E-mail adminofficer@idsc.co.uk or for membership

membership@idsc.co.uk, web: www.idsc-uk.co.uk

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