

# Loan Set Management Principles between Suppliers/Manufacturers, Theatres & Sterile Service Departments



## Introduction

These guidelines are intended to assist all parties in managing loan sets and provide a process whereby each loan event may be managed to the advantage of all parties. It will ensure that products are in the right place at the right time and in the right conditions.

They have been written with contributions from representatives of the three main actors in the loan set management process: theatres, sterile services departments and loan set suppliers.

The process outlined below provides a description of the entire process of loan set management. Each section covers the activity of theatre, the loan set supplier or the sterile services department. The intention is to allow each actor in the chain to understand the activities of the other parties and how they relate to the whole process. This process is set out graphically in Annex 2.

Annex 1 provides recommended timetables for notice, receipt of loan set record data and receipt of loan sets.

Annex 3 provides a model checklist from ordering to payment for use by Theatre.

Annexes 4 to 9 describe the process and provide checklists for theatre, SSD and suppliers individually.

Annex 10 provides useful references and contact details.

## The Process

### Theatre

### Sterile Service Department

### Manufacturer/Supplier

1. Theatre receives notification of surgery and a decision is made as to whether a loan set is required.
2. **In the case of emergency or trauma surgery, theatre will advise the SSD immediately the need for the use of a loan set is recognised. Both theatre and the SSD will use their best endeavours to expedite the ordering, supply, checking and processing of the loan set in order to minimise continuing patient risk of delay and cancellation. In such circumstances, the loan set will be regarded as a 'fast track' item, i.e. will take priority over elective loan sets which may be in process. Any delays in processing will be notified to the customer.**
3. When required for elective surgery, loan trays or sets are normally booked well in advance from the set supplier. Theatre should advise the Sterile Services Department as soon as it has done so and confirm the expected delivery date from theatre to the SSD. Theatre should provide SSD with information on loan sets that are unfamiliar to them. The SSD will maintain and make available a list of loan instrument sets with which it is familiar. [For sample timescales, see Annex 1 below].

4. Where the SSD is notified that the theatre intends to use a loan set that the SSD is unfamiliar with then the SSD will notify the theatre, within 24 hours, to arrange a longer process time to allow for training and processing. [For sample timescales, see Annex 1 below].
5. **In the case of emergency or trauma surgery, SSD will have been advised and should expedite all processes in order to minimise continuing patient risk as described above.**
6. Theatres contact the loan set 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. Theatres should be aware that additional time will be required to facilitate training for both theatre and SSD staff if an unfamiliar kit is involved.
7. Loan supplier confirms details of loan: instruments, implants, costs, dates of delivery and collection. Loan suppliers should be aware that first-time users may require extended loan times to allow for training in theatres and SSD.
8. Theatre confirms details with the SSD both verbally and in writing.  
NOTES:
  - Theatres should use all reasonable endeavours to inform the SSD at the earliest opportunity and, where practical, at least 48 hours ahead of the required time for the loan instrument sets to be available for use (provided that the equipment can be processed using standard UK decontamination processes).
  - The theatre should also use all reasonable endeavours to provide the SSD with the set no less than 48 hours before they are required for use.
  - The theatre should also give recognition to the additional time that may be required for loan instrument sets that are unfamiliar to the SSD. There may be special processing requirements (process compatibility review) or training requirements that are required to be organised as well as setting up of tray information on the IT system.
9. Loan supplier delivers instruments and implants to a specified location(s) for initial check by theatre. All deliveries should be accompanied by: delivery note, reprocessing instructions, decontamination certificate, detailed instrument tray lists, by tray 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 (see HSE Guidance – Getting to Grips with Manual Handling).
  - Reprocessing instructions should conform to EN ISO 17664 and should include disassembly diagrams where applicable.
  - Loan set suppliers should have a robust track-and-trace system for instrument trays. This will assist Trusts in the event they need to trace patients on whom the device has been subsequently used in the event of vCJD being diagnosed in an earlier patient.
  - Loan set suppliers should ensure that migration of instruments does not take place between sets. Instruments should be linked to trays with serial numbers.
10. On receipt at theatre, instruments and implants should be checked for completeness and any discrepancies should be notified to the loan set supplier immediately.
11. The SSD should also be informed of any potential delay.

12. Theatre sends checked and inspected instruments to SSD within the agreed timescale according to the hospital's procedures, confirming the date and time of the operation, and sending any documentation necessary as defined within this guidance. SSD to be informed by telephone call of the set's impending arrival.
13. SSD receives the instrument sets and documentation necessary for reprocessing:
  - Loan Tray Form: fully completed by theatre.
  - 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 EN ISO 17664: any special requirements for assembly/disassembly, lubrication or functional testing should be provided.
14. If the SSD finds any discrepancies in the loan set, such as damaged or missing instruments, the SSD will quarantine the set in an unprocessed condition for the theatre or loan set company to inspect. The SSD should alert theatre of the reason for the quarantine within 30 minutes of the discrepancies being discovered.
15. SSD establishes tray(s) on the IT system and generates tracking labels for theatre use in order to allow tracking back to the decontamination process.
16. Process instrument sets according to local procedures.
17. SSD dispatches loan sets and documentation (tray content sheet & loan tray form) to theatre.
18. Theatre inspects sets to ensure packaging is undamaged and sterility is not compromised.
19. Theatre checks immediately prior to procedure to ensure all instruments are present and in the correct tray location prior to use.
20. Operation performed.
21. Theatre takes responsibility for tracking tray details to the patient.
22. Theatre checks to ensure all instruments are present and in the correct tray location prior to return to SSD
23. Theatre completes usage form enclosed with the loan set supplier's documentation and reconfirm purchase order if necessary.
24. Theatre returns sets to SSD for reprocessing as per local procedures.
25. SSD 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 SSD then SSD ensures that sets are appropriately containerised/packaged and addressed for collection by supplier at the agreed time.) The SSD should ensure that migration of instruments does not take place between trays/sets while in their care.

26. SSD returns sets to theatre within the agreed timescale in readiness for collection by the supplier. Sets should be accompanied by decontamination certificates.
27. Theatre ensures sets are appropriately containerised/packaged and addressed for collection by supplier at the agreed time.
28. Supplier collects sets from theatre or pre-arranged point.

## **Recommended Timetables for Notice, Receipt of Loan Set Record Data and Receipt of Loan Kits**

The tables below give examples of timings for receipt both of trays familiar to the SSD and those that have not been seen before. These timings assume that the SSD is working 7 days, if this is not the case then they should be adjusted accordingly.

<b>Loan sets familiar to SSD</b>			
<b>Day of Clinical Use</b>	<b>Notice of Loan Set Requirement</b>	<b>Loan Set Record to be sent to SSD and Follow-up Telephone Call</b>	<b>Loan Set available for collection from the Customer (Theatre)</b>
Monday*	Wednesday 1 p.m.	Friday 1 p.m.	Friday 1 p.m.
Tuesday	Thursday 1 p.m.	Friday 8 a.m.	Friday 1 p.m.
Wednesday	Friday 1 p.m.	Monday 1 p.m.	Monday 1 p.m.
Thursday	Monday 1 p.m.	Tuesday 1 p.m.	Tuesday 1 p.m.
Friday	Tuesday 1 p.m.	Wednesday 1 p.m.	Wednesday 1 p.m.
Saturday*	Wednesday 1 p.m.	Thursday 1 p.m.	Thursday 1 p.m.
Sunday*	Wednesday 1 p.m.	Friday 9 a.m.	Friday 9 a.m.

<b>Loan sets to be processed for the first time on a specific site</b>			
<b>Day of Clinical Use</b>	<b>Notice of Loan Set Requirement</b>	<b>Loan Set Record to be sent to SSD and Follow-up Telephone Call</b>	<b>Loan Set available for collection from the Customer (Theatre)</b>
Monday*	Wednesday 1 p.m.	Wednesday 1 p.m.	Thursday 1 p.m.
Tuesday	Thursday 1 p.m.	Thursday 1 p.m.	Friday 1 p.m.
Wednesday	Friday 1 p.m.	Friday 1 p.m.	Monday 1 p.m.
Thursday	Monday 1 p.m.	Monday 1 p.m.	Tuesday 1 p.m.
Friday	Tuesday 1 p.m.	Tuesday 1 p.m.	Wednesday 1 p.m.
Saturday*	Wednesday 1 p.m.	Wednesday 1 p.m.	Thursday 1 p.m.
Sunday*	Wednesday 1 p.m.	Thursday 1 p.m.	Thursday 1 p.m.

**\* SSD should be notified by Theatre of all planned Loan Set requirements for Weekend and Monday use by Wednesday 1 p.m. at the latest.**

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**Loan Kit Order to Payment Model Checklist  
(Theatres)**

This model checklist, which should be tailored for individual circumstances, includes the end-to-end activities from ordering to payment regarding Loan Kit used in Theatres. In the example given, Theatres have a named individual/team in Theatres responsible for Materials Ordering (MO). This should be substituted with any local theatre terminology.

	<b>PROCESS DESCRIPTION</b>	<b>RESPONSIBILITY</b>	
<b>01</b>	Materials Ordering (MO) receive loan kit requirements from Department of Surgery/Theatres.	Theatre	<input type="checkbox"/>
<b>02</b>	MO creates a requisition on the organisations procurement system with estimated total cost, any hospital number and reference. This information is also recorded onto any loan kit sheet that is used as an audit trail within the Theatre.	MO/ Theatre	<input type="checkbox"/>
<b>03</b>	Responsible person in Theatres contacts the supplier and orders the loan kit with the requisition number given by MO.	Theatre	<input type="checkbox"/>
<b>04</b>	Suppliers send out the loan kit with the requisition number. Each loan kit order has one corresponding requisition number.	Loan Kit Suppliers	<input type="checkbox"/>
<b>05</b>	Responsible person in Theatres counts the contents of each loan kit before use and updates the count sheet.	Theatre	<input type="checkbox"/>
<b>06</b>	Responsible person in Theatres counts the contents of each loan kit after use and updates the count sheet before returning the loan kit to suppliers.	Theatre	<input type="checkbox"/>
<b>07</b>	MO completes the requisition with total line value of the loan kit and sends for approval. This information is updated back onto the loan kit sheet.	MO	<input type="checkbox"/>
<b>08</b>	Department of Surgery/Theatres review the requisition and approve if agree. Return the requisition to MO otherwise.	Department of Surgery/Theatres	<input type="checkbox"/>
<b>09</b>	Hospital Supplies Department issue and confirm the purchase order against the approved requisition.	Hospital Supplies Department	<input type="checkbox"/>
<b>10</b>	Responsible person in Theatres will complete the goods receipt for each purchase order. This information is updated back onto the loan kit sheet.	Theatre	<input type="checkbox"/>
<b>11</b>	Suppliers send invoices quoting requisition number to organisations payment/finance department.	Loan Kit Suppliers	<input type="checkbox"/>
<b>12</b>	Organisations payment/finance department reconcile the invoice to goods receipt and authorise payment.	Payment/finance department	<input type="checkbox"/>

### **Process for Theatres**

1. Theatre receives notification of surgery and a decision is made as to whether a loan set is required.
2. **In the case of emergency or trauma surgery, theatre will advise the SSD immediately the need for the use of a loan set is recognised. Both theatre and the SSD will use their best endeavours to expedite the ordering, supply, checking and processing of the loan set in order to minimise continuing patient risk of delay and cancellation. In such circumstances, the loan set will be regarded as a 'fast track' item, i.e. will take priority over elective loan sets which may be in process. Any delays in processing will be notified to the customer.**
3. When required for elective surgery, loan trays or sets are normally booked well in advance from the set supplier. Theatre should advise the Sterile Services Department as soon as it has done so and confirm the expected delivery date from theatre to the SSD. Theatre should provide SSD with information on loan sets that are unfamiliar to them. The SSD will maintain and make available a list of loan instrument sets with which it is familiar. [For sample timescales, see Annex 1].
4. Theatres contact the loan set 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. Theatres should be aware that additional time will be required to facilitate training for both theatre and SSD staff if an unfamiliar kit is involved.
5. Theatre confirms details with the SSD both verbally and in writing.  
NOTES:
  - Theatres should use all reasonable endeavours to inform the SSD at the earliest opportunity and, where practical, at least 48 hours ahead of the required time for the loan instrument sets to be available for use (provided that the equipment can be processed using standard UK decontamination processes).
  - The theatre should also use all reasonable endeavours to provide the SSD with the set no less than 48 hours before they are required for use.
  - The theatre should also give recognition to the additional time that may be required for loan instrument sets that are unfamiliar to the SSD. There may be special processing requirements (process compatibility review) or training requirements that are required to be organised as well as setting up of tray information in the IT system.
6. On receipt at theatre, instruments and implants should be checked for completeness and any discrepancies should be notified to the loan set supplier immediately.
7. The SSD should also be informed of any potential delay.
8. Theatre sends checked and inspected instruments to SSD within the agreed timescale according to the hospital's procedures, confirming the date and time of the operation, and sending any documentation necessary as defined within this guidance. SSD to be informed by telephone call of the set's impending arrival.
9. Theatre inspects sets to ensure packaging is undamaged and sterility is not compromised.

10. Theatre checks immediately prior to procedure to ensure all instruments are present and in the correct tray location prior to use.
11. Operation performed.
12. Theatre takes responsibility for tracking tray details to the patient.
13. Theatre checks to ensure all instruments are present and in the correct tray location prior to return to SSD
14. Theatre completes usage form enclosed with the loan set supplier's documentation and reconfirm purchase order if necessary.
15. Theatre returns sets to SSD for reprocessing as per local procedures.
16. Theatre ensures sets are appropriately containerised/packaged and addressed for collection by supplier at the agreed time.

### Checklist for Theatres

	Process Description	
1.	Decide on need for loan set	<input type="checkbox"/>
2.	<b>FOR EMERGENCY OR TRAUMA SURGERY, NOTIFY SSD IMMEDIATELY AND EXPEDITE ALL PROCESSES</b>	<input type="checkbox"/>
3.	Advise SSD on expected delivery date from theatre along with information on type of loan set to be provided	<input type="checkbox"/>
4.	Contact loan set supplier in good time to allow for delivery, checking, reprocessing and training if required. Provide Purchase Order Number.	<input type="checkbox"/>
5.	Confirm details with SSD both verbally and in writing	<input type="checkbox"/>
6.	Check instrument sets and implants for completeness and notify loan set company of any discrepancies.	<input type="checkbox"/>
7.	Notify SSD of any delay due to incompleteness of instrument sets.	<input type="checkbox"/>
8.	Send checked and inspected instruments to SSD along with any documentation necessary. Confirm date and time of operation to SSD. SSD to be notified by phone of instrument dispatch.	<input type="checkbox"/>
9.	Inspect sets to ensure packaging integrity and assure sterility.	<input type="checkbox"/>
10.	Check that all instruments are present, in the correct tray and in the correct tray location.	<input type="checkbox"/>
11.	Operation performed.	<input type="checkbox"/>
12.	Track tray details to patient.	<input type="checkbox"/>
13.	Check that all instruments are present, in the correct tray and in the correct tray location.	<input type="checkbox"/>
14.	Complete supplier's usage form and reconfirm purchase order if necessary.	<input type="checkbox"/>
15.	Return sets to SSD for reprocessing.	<input type="checkbox"/>
16.	Ensure loan sets are appropriately containerised/packaged and addressed for collection by supplier at the agreed time.	<input type="checkbox"/>

## **Process for Sterile Service Departments**

1. To allow adequate time for processing prior to use by theatre, it is important that the loan set and the required information is supplied to the SSD according to the timescale set out below. Where the SSD is notified that the theatre intends to use a loan set that the SSD is unfamiliar with then the SSD will notify the theatre, within 24 hours, to arrange a longer process time to allow for training and processing. [For sample timescales, see Annex 1].
2. **In the case of emergency or trauma surgery, SSD will have been advised and should expedite all processes in order to minimise continuing patient risk.**
3. If the SSD finds any discrepancies in the loan set, such as damaged or missing instruments, the SSD will quarantine the set in an unprocessed condition for the theatre or loan set company to inspect. The SSD should alert theatre of the reason for the quarantine within 30 minutes of the discrepancies being discovered.
4. SSD receives the instrument sets and documentation necessary for reprocessing:
  - Loan Tray Form: fully completed by theatre.
  - 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 EN ISO 17664: any special requirements for assembly/disassembly, lubrication or functional testing should be provided.
5. SSD establishes tray(s) on the IT system and generates tracking labels for theatre use in order to allow tracking back to the decontamination process.
6. Process instrument sets according to local procedures.
7. SSD dispatches loan sets and documentation (tray content sheet & loan tray form) to theatre.
8. SSD 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 SSD then SSD ensures that sets are appropriately containerised/packaged and addressed for collection by supplier at the agreed time.) The SSD should ensure that migration of instruments does not take place between trays/sets while in their care.
9. SSD returns sets to theatre within the agreed timescale in readiness for collection by the supplier. Sets should be accompanied by decontamination certificates.

**Checklist for Sterile Service Departments**

	<b>Process Description</b>	
<b>1.</b>	Notify theatre of longer processing time if an unfamiliar set is involved.	<input type="checkbox"/>
<b>2.</b>	<b>FOR EMERGENCY OR TRAUMA SURGERY, EXPEDITE ALL PROCESSES</b>	<input type="checkbox"/>
<b>3.</b>	Quarantine any sets with discrepancies, e.g. missing or damaged instruments. Inform theatre within 30 minutes and arrange for unprocessed set inspection by theatre and/or loan set supplier.	<input type="checkbox"/>
<b>4.</b>	Receive instrument sets 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).	<input type="checkbox"/>
<b>5.</b>	Establish instrument sets on the IT system and generate tracking labels for theatre use.	<input type="checkbox"/>
<b>6.</b>	Process instrument sets according to local procedures.	<input type="checkbox"/>
<b>7.</b>	Dispatch loan sets and documentation to theatre.	<input type="checkbox"/>
<b>8.</b>	Reprocess sets according to local procedures. Ensure that trays are free of locally-fixed tape and/or labels.	<input type="checkbox"/>
<b>9.</b>	Return sets to theatre within the agreed timescale for collection by supplier. Decontamination certificates should accompany sets.	<input type="checkbox"/>

### **Process for Loan Kit Suppliers**

1. Loan supplier confirms details of loan: instruments, implants, costs, dates of delivery and collection. Loan suppliers should be aware that first-time users may require extended loan times to allow for training in theatres and SSD.

2. Loan supplier delivers instruments and implants to a specified location(s) for initial check by theatre. All deliveries should be accompanied by: delivery note, reprocessing instructions, decontamination certificate, detailed instrument tray lists, by tray 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 (see HSE Guidance – Getting to Grips with Manual Handling).
- Reprocessing instructions should conform to EN ISO 17664 and should include disassembly diagrams where applicable.
- Loan set suppliers should have a robust track-and-trace system for instrument trays. This will assist Trusts in the event they need to trace patients on whom the device has been subsequently used in the event of vCJD being diagnosed in an earlier patient.
- Loan set suppliers should ensure that migration of instruments does not take place between sets. Instruments should be linked to trays with serial numbers.

3. Supplier collects sets from theatre or pre-arranged point.

**Checklist for Loan Kit Suppliers**

	<b>Process Description</b>	
<b>1.</b>	Confirm details of loan: instruments, implants, costs, dates of delivery and collection. Allow for extended loan time for first-time users.	<input type="checkbox"/>
<b>2.</b>	Deliver loan set for checking by theatre. Include delivery note, reprocessing instructions, decontamination certificate, tray lists and, where possible, product codes and photographic documentation	<input type="checkbox"/>
<b>3.</b>	Collect sets from theatre or pre-arranged point	<input type="checkbox"/>

## **List of References & Contacts**

### **EN ISO 17664: 2004**

Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

### **Getting to grips with manual handling – A short guide**

[www.hse.gov.uk/pubns/indg143.pdf](http://www.hse.gov.uk/pubns/indg143.pdf)

### **ABHI**

Association of British Healthcare Industries, 111 Westminster Bridge Road, London, SE1 7HR  
Tel: +44 (0)20 7960 4360, Fax: +44 (0)20 7960 4361, Email: [enquiries@abhi.org.uk](mailto:enquiries@abhi.org.uk),  
Web: [www.abhi.org.uk](http://www.abhi.org.uk)

### **AfPP**

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North Yorkshire, HG1 4DP  
Tel: +44 (0)1423 508079, Fax: +44 (0)1423 531613,  
Email: [www.afpp.org.uk/contact-us/contact-us](http://www.afpp.org.uk/contact-us/contact-us), web: [www.afpp.org.uk](http://www.afpp.org.uk)

### **IDSc**

Institute of Decontamination Sciences, c/o Fitwise Management Limited, c/o Fitwise  
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