NHS National Services Scotland

NHSScotland Guidance Management of on Loan Reusable Surgical Instruments Roles and Responsibilities

Scottish Health Technical Memorandum 01-08

SHTM 01-08

Version 1 - September 2025

Contents

Executive Summary

The National Guidance 'Management of on Loan Reusable Surgical Instruments Roles and Responsibilities' has been revised to be in line with the latest Regulations, lesson learned from incidents and emerging issues. The title of this document has been changed to Scottish Health Technical Memorandum (SHTM) 01-08 to better align this reusable medical device decontamination guidance with other parts of the SHTM 01 series.

The aim of the guidance is to ensure on loan surgical instruments are delivered to theatre fit for purpose, on time and returned safely to the supplier.

This guidance includes roles and responsibilities for theatres, Central Decontamination Units (CDUs) (sometimes referred to as Sterile Service departments) and manufacturers/ suppliers. It also covers the on-loan cycle from the decision to order an on loan surgical instruments to returning the on loan surgical instruments to the supplier.

In this context, to minimise the risk of any cross contamination, the manufacturers/ suppliers is obliged to ensure any on loan instruments have only been used in the treatment of humans. Tracking and traceability measures must be in place to prevent veterinary instruments entering the CDU/ theatres workstream (see ref 1). Evidence should also be available to show that all on loan instruments have been appropriately processed prior to delivery/ use.

Healthcare facilities, for example operating theatres, may use on loan surgical instruments to provide additional inventory for a range of procedures. Where on loan devices are required frequently, consideration should be given to increasing the buffer stock held by a service. This would help provide devices with a known decontamination history while supporting NHSScotland's climate emergency and sustainability strategy: 2022-2026 Net Zero strategy (see ref 2).

Additional information on a systematic approach to the acquisition, deployment, maintenance, repair and disposal of on loan surgical instruments and medical device training can be found in Scottish Health Technical Note (SHTN) 00-04 Guidance on Safe Management of Medical Devices and Equipment in Scotland's Health and Social Care Services Version 3, published in 2024 (see ref 3).

1. Background

Who is this guidance for?

1.1. This guidance aims to assist those responsible for, or involved with, the distribution/ supply, acquisition and decontamination of on loan reusable surgical instruments. This includes the suppliers/ manufacturers, theatre and decontamination staff.

Aim of the guidance

1.2. The aim of the guidance is to ensure that on loan surgical instruments are delivered to theatre fit for purpose, in a timely manner and returned safely to the supplier. Delivering a positive health impact by ensuring that on loan instruments are:

- safe
- available at the designated time
- managed by staff trained in reprocessing on loan instruments
- reprocessed, packaged and transported in a manner that complies with the UK Medical Device Regulations (MDR) 2002 (see ref 4) (Amendment) (EU Exit) Regulations 2020)
- reprocessed, packaged and transported in a manner to prevent damage to instruments and risks to staff
- returned to the supplier in a safe and decontaminated state

1.3. The lack of clear guidance could result in delayed and cancelled patient treatment, injury and cross infection. A review of Safety Action Notices (SANs) and Patient Safety Action Notices (PSAN) published by Incident Reporting and Investigation Centre (IRIC) and Medicines and Healthcare Products Regulatory Authority (MHRA) (see ref 5, 6 and 7) identified that some processed instruments have been released to clinical areas in an unsterile state. In addition, there was occasions where on loan instruments were delivered by the suppliers to Central Decontamination Units (CDUs) in an unclean, damaged/ corroded conditions.

1.4. Moreover, evidence shows that effective control of on loan instruments continues to present challenges to theatres, clinics, sterile services, manufacturers'/ suppliers. Lapses in planning, policies, communications and instructions (see refs 8, 9 and 10) were found to have contributed to the risks associated with on loan instruments.

1.5. Furthermore, on loan instruments may include many complex instruments which could be new or unfamiliar to CDU staff and require additional time to validate the decontamination process and provide staff training (see ref 11 and 12).

Scope

1.6. This guidance is applicable to on loan instruments that are processed in a CDU, for examples:

- instrument sets in reusable containers or trays
- individual instruments packaged as sterile
- robotic instruments
- non sterile instruments requiring processing in an NHS CDU (see ref 3, 11 and 12) or, a contracted sterilization services registered with MHRA).

Out of scope

1.7. Loan of other medical devices, such as thermolabile flexible endoscopes or endocavity probes, are not processed in a CDU.

1.8. Loan devices that are processed in a Local decontamination Unit (LDU).

2. Theatre/ clinic roles and responsibilities

Factors to consider before acquisition

2.1. The overall responsibility for management of on loan reusable surgical instruments resides with the operating theatres requesting the instruments (see ref 13). This covers all stages of the process, from assessing the requirements for on loan instruments, to returning them to the supplier. Whenever possible the need for on loan instruments should be identified as soon as possible by theatre teams.

2.2. There should be a Service Level Agreements (SLAs) between the NHS boards and the suppliers or manufacturers. The SLA defines the requirements of on loan instruments during acquisition, deployment, decontamination and return to the supplier (see ref 12). Any responsibilities or liabilities for maintenance, repair and disposal of instruments, should also be included.

2.3. Scottish Health Technical Note (SHTN) 00-04 Guidance on Safe Management of Medical Devices and Equipment in Scotland's Health and Social Care Services V3 published in 2024 (see ref 3) outlines a systematic approach to the acquisition, deployment, maintenance, repair and disposal of medical devices and medical device training. Medicines and Healthcare Products Regulatory Authority (MHRA) Managing Medical Devices 2021 (see ref 14) also provides guidance for manufacturers and suppliers of medical devices.

Emergency or trauma case

2.4. Where additional on loan instruments are required for emergency or trauma procedures, inform the Central Decontamination Units (CDUs) of the type of device requested and specify that they should be regarded as high priority and 'fast tracked' to expedite their supply, checking and processing.

Staff education and training

2.5. Ensure staff have a full understanding of on loan instruments policies and procedures. Additional time may be required for processing on loan instruments that are unfamiliar to theatre or CDU staff. Co-ordinate with all interested parties to enable the supplier's trainer to deliver training and update as required.

2.6. Ensure the manual handling regulations (see ref 15) Infection Prevention and Control (IP&C) measures (see ref 16) are included in the training.

Ordering on loan surgical instruments

2.7. Staff responsible for sourcing on loan instruments, for example surgical instrument coordinator, should discuss the requirements with the clinical team/ surgeon prior to ordering.

2.8. Theatre staff should inform the supplier and CDU, as soon as they are aware of the need for on loan instruments.

2.9. On ordering the on loan surgical instruments:

- request the manufacturer instructions for use (IFU)
- before the order is placed, forward the IFU to the CDU for approval to confirm that they can be processed by the CDU
- specify quantities and time of delivery
- inform CDU when the order has been confirmed
- for new or unknown sets where possible arrange for CDU to receive the instruments seven days before the procedure
- for known sets, arrange for CDU to receive the instruments at least 48 hours prior to planned procedure time
- raise purchase order

Pre-operative checks

2.10. On arrival of the on loan instruments from the supplier and before opening any protective packaging check that:

- all requested instrument sets are present and of the correct specification
- there are no signs of staining, contamination or damage

2.11. Where an on loan set was requested as ‘sterile’, check any protective packaging is intact and that labelling is consistent with the requirements for ‘sterile’ product, as stated in the relevant British standards (see refs 17, 18 and 19).

2.12. Where an instrument is supplied nonsterile, it should be accompanied by a decontamination certificate from the previous user stating the level and type of decontamination undertaken.

2.13. Prior to sending to the CDU for reprocessing, the following documents should be available:

- indemnity certificate
- IFU (including any validated decontamination process)
- list of tray contents or images of each device with name for each tray

2.14. Advise the supplier of any discrepancies immediately.

2.15. When introducing on loan instruments onto the theatre register or electronic tracking system (preferred) for traceability:

- identify and tag the surgical instruments as: 'On Loan'
- track on loan surgical instruments details to the patient
- prevent on loan surgical instrument set migration in theatre

Post operative checks

2.16. Where on loan sterile instrument sets in were not used nor opened in theatre, they can be retained by theatre, ready to return to the supplier. The CDU should be informed.

2.17. Prior to returning any surgical instruments to the CDU for reprocessing after use:

- all opened surgical instruments and sets remain intact and no migration of instruments between sets
- all surgical instruments are returned to the CDU after use
- on loan instrument sets and the associated documents are complete and in order
- allow the CDU at least 48 hours to process and issue decontamination certificates

Returning on loan surgical instruments to a supplier

2.18. Before returning on loan surgical instruments to the supplier:

- ensure protective packaging is intact and sterility has not been compromised, and the package has been labelled as sterile upon delivery from CDU
- the surgical instrument set is packaged appropriately, to prevent damage on return to supplier
- include the agreed tracking and traceability information
- arrange uplift by supplier as agreed and sign off in the theatre tracking system

Note 1: Where the instrument cannot be steam sterilised, decontaminate as agreed with the manufacturer or supplier and in line with the IFUs. Complete a decontamination certificate stating the type and level of decontamination carried out after use, for example manual cleaning or disinfection.

Reporting non-conformances, complaints and incidents

2.19. Report non-conformances or other complaints to the relevant parties (theatre manager, CDU manager and/ or supplier) within 48 hours.

2.20. In the event of an incident/ defect, immediately complete any local reporting system and notify:

- the manufacturer/ supplier
- theatre and CDU managers
- IP&C team
- Incident Reporting and Investigation Centre (IRIC)

2.21. Where a complaint is received from the CDU or supplier:

- acknowledge within one working day
- agree a plan of corrective actions
- complete actions within the agreed timescale with the complainant
- retain all communications, and electronic records, as per local policy and Scottish Government Records Management: NHS Code of Practice (Scotland) (see ref 20)

Additional responsibilities for 'medium or high risk' Creutzfeldt Jakob disease patients

2.22. Prior to any request for on loan surgical instrument which may be used for medium or high risk Creutzfeldt-Jakob disease (CJD) procedures, theatre staff should follow the Advisory Committee on Dangerous Pathogens (ACDP) Transmissible Spongiform Encephalopathy (TSE) guidance - Annex J: 2014 (See ref 21) on identifying patients who have been notified that they are at increased risk of CJD/ Variant Creutzfeldt-Jakob disease (vCJD).

2.23. If the patient, family member or representative cannot provide a definitive answer regarding CJD/ vCJD status, the surgical instruments should be cleaned as per ACDP TSE guidance Annex E (see ref 22), kept moist before cleaning, and sent to the CDU for processing as soon as the procedure ends, then quarantined until the patient's status is confirmed.

2.24. Surgical instruments that come into contact with medium and high-risk tissues must not be moved from one set to another and must remain within their individual sets (see ref 23). Maintaining set integrity reduces the risks associated with instrument migration (including infection) and makes it easier to trace instruments back to the patients.

Record keeping

2.25. All electronic and paper records should be maintained and archived in line with local policy and the Scottish Government Records Management: NHS Code of Practice (Scotland) (see ref 20).

3. CDU roles and responsibilities

3.1. Prior to agreeing to process on loan surgical instruments, Central Decontamination Units (CDU) should ensure that all on loan instruments are compatible with their existing decontamination processes, and staff are competent to perform decontamination procedure as per instructions for use (IFU).

3.2. When unfamiliar on loan surgical instruments are received, ensure a full understanding of the supplier's reprocessing instruction additional training and processing time may be required. Advise theatre if on-site training is required.

3.3. Upon arrival of the on loan instruments, confirm and check:

- the instrument has never been used on veterinary or other than human
- all requested on loan instruments and documents are present
- disassemble in line with IFU and inspect for contamination, corrosion and assess if the instrument is considered difficult to clean

3.4. If a discrepancy occurs, notify theatre as soon as possible (preferably within an hour of receipt). Quarantine and arrange for theatre, supplier and/ or manufacturer to inspect.

Management of on loan devices in CDU

3.5. All on loan instruments must be tracked through the CDU decontamination process. On arrival at the CDU, allocate a Unique Device Identification (UDI) Number then enter the instrument details onto CDU tracking system to prevent tray migration of on loan instruments throughout process.

3.6. On loan instruments must be decontaminated using CDU validated procedures and in accordance with written manufacturer's processing instructions.

3.7. Sterile instruments should be appropriately labelled and packaged before sending to theatre, accompanied with a list of the contents of each set.

3.8. Before returning to the suppliers, on loan instruments should be decontaminated and packed according to IFU and Service Level Agreement (SLA), The Decontamination certificate stating the level and type of decontamination should be included in the package.

3.9. All surgical instruments that come into contact with medium and high-risk tissues during an interventional procedure must be kept moist and separated from other instruments until they are cleaned, and then disinfected and sterilised (decontaminated) (see ref 23).

3.10. Surgical instruments that come into contact with medium and high-risk tissues must not be moved from one set to another and must remain within their individual sets (see ref 23).

In emergency or trauma cases

3.11. Theatre requests processing of on loan instruments for an emergency or trauma surgery, if possible:

- expedite the checking, processing and delivery of on loan surgical instruments
- regard devices as a priority
- notify theatres of any issues or delays as soon as possible

Reporting non-conformances, and incidents

3.12. In the event of an incident/ defect, immediately notify:

- the manufacturer/ suppliers
- theatres and any local reporting system
- Infection Prevention and control (IP&C) team
- Incident Investigation and Reporting Centre (IRIC)

3.13. Raise complaints and non-conformities with the relevant parties (theatres, supplier and/ or manufacturer) within 48 hours and:

- record the event in the CDU quality system as a non-conformance
- undertake a Corrective Action and Preventative Action (CAPA) plan within the Quality Management System (QMS) (see ref 18) and monitor trends
- report through local decontamination governance procedure receiving a complaint

3.14. Where a complaint is received from the device supplier or theatre:

- acknowledge within one working day
- propose corrective actions with the complainant
- complete actions within the agreed timescale

Record keeping

3.15. Maintain and archive paper and electronic records in accordance with QMS and Scottish Government Records Management: NHS Code of Practice (Scotland) (see ref 20).

4. Supplier roles and responsibilities

Service level agreement

4.1. Manufacturers supplying on loan surgical instruments should be registered with Medicines and Healthcare Products Regulatory Authority (MHRA) and accredited to and have a Quality Management System (QMS) certified to British Standard BS EN ISO 13485. Where a Service Level Agreement (SLA) is in place suppliers are responsible for providing safe, fit for purpose and traceable on loan reusable instruments to agreed timescales.

4.2. Provide on loan instruments meeting the required standard and quality as follows:

- intended or have been used only for human use
- cleanliness, functionality and completeness are checked and satisfactory
- package appropriately
- compliance with the facility's handling policy
- must be **CE** or **UKCA** marked unless exempt, for example custom made devices (see ref 4 and 24)

Staff education and training

4.3. Provide training to Central Decontamination Unit (CDU)/ theatre staff on the handling, use and reprocessing of unfamiliar instruments, as requested.

4.4. Provide full supporting documentation including:

- instructions for use (IFU) including reprocessing instructions conforming to BS EN ISO 17664 (see ref 17)
- a decontamination certificate where the device is not sterile
- a detailed tray lists for the on loan surgical instruments
- product codes and photographic documentation as necessary
- a delivery note

4.5. Weight of the on loan surgical instruments must not present a manual handling risk.

4.6. The on loan instruments are managed and controlled using a robust tracking system.

Rectifying supply discrepancies

4.7. Where a signed indemnity agreement is in place, follow the master terms and conditions. Ensure an immediate supply of a replacement surgical instrument or, inform theatre and CDU of the length of any delay where anticipated.

4.8. Prior to uplift, check the on loan instrument has been processed has an accompanying decontamination certificate and is safe to handle. Where a surgical instrument is not suitable for sterilization ensure that a decontamination certificate has been provided and shows the agreed decontamination method has been carried out.

4.9. Sign off request, as agreed with customer (theatres or CDU as relevant).

Reporting non-conformances, complaints and incidents

4.10. In case of a defect, or where a non-conformity is discovered on return of the on loan surgical instrument report and raise complaints directly to the relevant parties (Theatres and/ or CDU) within 48 hours.

Receiving complaints

4.11. Where a complaint is received from the CDU or theatre:

- acknowledge within one working day
- propose corrective actions
- agree corrective action with the complainant and complete within the agreed timescale

4.12. Where an incident has occurred:

- inform the National Services Scotland (NSS), Incident Investigation and Reporting Centre (IRIC) and MHRA
- maintain communication with all parties until the issues have been satisfactorily resolved
- maintain and archive paper and electronic records in accordance with BS EN ISO 13485: 2021 Quality Management System (See ref 18)
- notify the hospital/ NHS board immediately, for any previous incidents affecting the quality of instruments that are loaned to the hospital. For example, the instruments were previously used on a patient that later found to be at-risk of Creutzfeldt-Jakob disease (CJD).

Abbreviations

ACDP: Advisory Committee on Dangerous Pathogens

BS: British Standard

BSI: British Standards Institution

CAPA: Corrective Action and Preventative Action

CDU: Central Decontamination Unit scope of decontamination activities

CJD: Creutzfeldt Jakob disease

IFU: Instruction for use

IP&C: Infection Prevention and Control

IPC: Interventional Procedures Guidance

IRIC: Incident Reporting and Investigation Centre

LDU: Local decontamination Unit

MDR: Medical Device Regulations

MHRA: Medicines & Healthcare products Regulatory Agency

NIPCM: National Infection Prevention and Control Manual

NICE: National Institute for Healthcare Excellence

NSS: National Services Scotland

PSAN: Patient Safety Action Notices

QMS: Quality Management System

RA: Regulatory Authority

SAN: Safety Action Notice

SHPN: Scottish Health Planning Note

SHTM: Scottish Health Technical Memorandum

SHTN: Scottish Health Technical Note

SLA: Service Level Agreement

TSE: Transmissible Spongiform Encephalopathy

UDI: Unique Device Identification

vCJD: Variant Creutzfeldt-Jakob disease

Glossary

Complaint - written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices.

Corrective action - action to eliminate the cause of a nonconformity and to prevent recurrence.

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

Disinfection - process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose instructions for use (IFU) portion of the accompanying information that is essential for the safe and effective intended use of a medical device or accessory directed to the user of the medical device.

Labelling - label, IFU, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping document.

Life-cycle - all phases in the life of a medical device, from the initial conception to final decommissioning and disposal.

Manual cleaning - removal of contaminants from an item to the extent necessary for further processing or for intended use without the use of an automated process.

Medical device - material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury
- investigation, replacement, modification, or support of the anatomy, or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological,

immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions, but not in others include:

- items specifically intended for cleaning or sterilization of medical devices
- pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization
- disinfection substances
- aids for persons with disabilities
- devices incorporating animal and/ or human tissues
- devices for in vitro fertilization or assisted reproduction technologies

Medical device manufacturer - natural or legal person with responsibility for design and/ or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/ or manufactured by that person himself or on his behalf by another person(s).

Note 1 to entry: This “natural or legal person” has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Processing - preparation of medical device, accessory - activity to prepare a new or used medical device or accessory for its intended use.

Protective packaging - configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use.

Reusable medical device - medical device (3.5) designated or intended by the medical device manufacturer (3.6) as suitable for processing (3.8) and reuse.

Note 1 to entry: This is not a medical device that is designated or intended by the manufacturer for single use only.

Sterile - free from viable microorganisms.

Unique Device Identification (UDI) - a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market.

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