NHS National Services Scotland

Theatres and CDU Guidance

Management of reusable surgical instruments during transportation, storage and after clinical use – GUID 5010

Part B – Operational guidance

Health Facilities Scotland
Decontamination Services

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1. Introduction

1.1 The development of this guidance was via stakeholder consultation. The stakeholders included members of the Sterile Services Department Consultative Group, Infection Control Managers and clinical representatives such as Theatre Managers. Stakeholder brief consultation exercises with the Service were organised in May and July 2013 to inform the user requirement brief for the development of this new guidance. The brief was finalised in July 2013.

The principal theme within the guidance is raising awareness of the fragile nature of the sterile packs/trays and the used instruments/packs/trays and the resulting need to handle with care.

This guidance has been informed from a variety of feedback from the Service. Recognising that given the complexity of this subject there will not be a single solution that fits all circumstances this guidance is supplemented with things to avoid and things to consider for improvement. This is intended to enable the sharing of Service experiences of both failures and successes with the intention of improving nationally the future overall quality of sterile packs/trays used in patient care.

A separate document (GUID 5010 Part A – Design guidance) an advice note for planning is concerned with the room design requirements for storage of sterile packs/trays in clinical facilities. The advice note for planning is aimed at designers, estates and clinical staff.

Note: This operational guidance is intended principally for Theatre staff. Where a section is labelled 'All Staff' this refers to all who may handle the sterile packs/trays or the used instruments packs/trays. If relevant to other staff groups, such as CDU staff, this will be stated at the start of the relevant guidance section.

[A handling precautions notice for sterile packs/trays is given in Appendix 2. This may be printed A4 and be attached to transport carts/boxes or printed A3 and laminated to be used as a wall notice.]

An example of a CDU/Theatre agreement on provision of sterile packs/trays is given for consideration in Appendix 1.

This guidance is provided based on existing European standards and best practice guidance. This is supported by "things to consider" and "avoid" as feedback experiences from the Service.

Purpose

1.2 The operational guidance for theatre staff is concerned with the handling of sterile packs/trays received from the Central Decontamination Unit (CDU) and the handling of surgical instruments after use and transport to the CDU.

The operational guidance is intended for staff who have responsibility for receiving, storing and using sterile pack/trays (e.g. theatre managers, stores personnel, theatre staff and porters).

Scope

1.3 The operational guidance covers the following process of reusable surgical instruments after leaving and before returning to/from Central Decontamination Units.

- handling of sterile packs/trays on arrival at theatres;
- transport of sterile packs/trays - both internal and external transport to the hospital;
- storage of sterile packs/trays before use;
- handling of used instruments/packs/trays after use including pre cleaning;
- disposal of non standard items, e.g. packaging;
- storage of used instruments/trays/packs prior to despatch to CDU;
- internal transport of used instruments/trays/packs.

Exclusions

1.4 Single use instruments and other medical devices used in theatre but not decontaminated in a CDU are excluded.

Other activities within a CDU and the use of instruments in the clinical area are excluded. The following storage areas in theatres are excluded - material stores, implant stores and equipment storage areas.

External transport of used instruments/trays/packs though in the scope of the published brief is now excluded. Reference can be made to the NHSScotland guide to the carriage of dangerous goods regulations with respect to used medical devices published by HFS in December 2013.

2. Operational Guidance for Theatre staff (and/or others where indicated)

Handling of sterile packs/trays

For all staff

2.1 All sterile packs/trays need to be handled in a manner which will not compromise their sterile condition, enable aseptic presentation in use and be handled in accordance with the manufacturer's instructions[1].

2.2 Many sterile packs/trays require careful handling as they contain expensive and delicate instruments[1]. Some sterile packs/trays can be heavy, have an asymmetrical mass distribution and be of a size that is difficult for an individual person to handle.

2.3 Handling precautions for sterile packs/trays to be followed at all times (for example see Appendix 2) should be highly visible on entering the theatre suite and at all the sterile packs/trays storage locations.

2.4 Sterile packs/trays that are wrapped should not be dragged across shelving or racking and should not be lifted or pulled by their protective wrap.

2.5 Sterile packs/trays need to be kept dry and must not be torn, punctured or otherwise damaged[1].

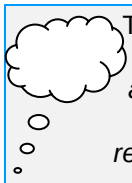
Avoid:

When inspecting the protective packaging and or the sterile barrier packaging the sterile pack/tray should not be turned on its side as instruments may become disorganised and/or damaged.

2.6 All personnel who will be required to handle sterile packs/trays (such as porters, drivers, SSD assistants, phlebotomists, nurses, clinicians) should receive appropriate training in the correct handling procedures and why they are necessary ie for the protection of patient and staff[1&2].

2.7 Manual handling regulations should be followed.
http://www.hse.gov.uk/msd/pushpull/regulations.htm

2.8 Where untrained persons handle sterile packs/trays there should be an agreed protocol for alerting them that, if applicable, the sterile pack/tray is fragile and must be handled with care.



Things to consider:

a) Certified training in handling procedures should be conducted regularly e.g. annually or as required for new products.

b) New start theatre personnel undergoing induction should receive training in the use, handling and storage of instruments.

c) A dedicated stores person (has been reported as being beneficial).

2.9 All pre-sterilised articles (sterile packs/trays) should be checked for evidence of sterilization, damage, the integrity of packaging system (see glossary) and expiry date prior to use[3].

2.10 Rejected items should be returned to the CDU in line with local agreement (see example CDU/ Theatre agreement in Appendix 1).

Things to consider:

Have a clear process describing the responsibilities for CDU and theatre staff in the reporting and replacement of damaged product.

2.11 The hands of personnel who will handle sterile packs/trays need to be clean and dry[1].

2.12 Hand hygiene must be carried out prior to handling sterile packs/trays as per Standard Infection Control Precautions (SICPs) detailed in the HPS National Infection Prevention and Control Manual[5].

http://www.hps.scot.nhs.uk/haiic/ic/nationalinfectionpreventionandcontrolmanual.aspx

Transport of sterile packs/trays

For Theatre and CDU staff

2.13 There should be documented procedures for delivery[1] (see example CDU/Theatre agreement in Appendix 1).

Things to consider:

a) Have a clear process describing the responsibilities for CDU and theatre staff once sterile packs/trays are receipted by Theatres.

b) The process may include a timeline for reporting defaults. See the example CDU/Theatre agreement in Appendix 1.

2.14 Sterile packs/trays being delivered must be segregated from used goods being returned[1].

2.15 Each sterile pack/tray to be loaded onto a trolley or into a transit container should be inspected and handled with care; packs should not be crushed together[1].

2.16 Cramming additional sterile packs/trays into too small a space will invariably result in damage[2].

2.17 Trolleys should be labelled “sterile”.

Things to consider:

a) Have a clear notice on the transport carts/boxes - “Handle with Care”;

b) The use of shelf dividers to restrict movement of the sterile packs/trays in transport.

c) Consider the use of the notice in Appendix 2.

2.18 Trolleys used for distribution **within** the hospital should be covered or closed with a solid bottom shelf[1].

2.19 Containers, distribution trolleys and any surfaces in theatre on which the sterile packs/trays will be placed must be in good condition, clean and dry[3].

Avoid:

When transporting sterile packs/trays that are wrapped avoid the use of cart shelves/inner walls with rough surfaces which may tear the protective packaging. (See Figure 1 for an example of what to avoid).

Figure 1: a transport cart showing signs of ageing with rough internal surfaces that may tear wrap when loading/unloading wrapped sterile packs/trays.

For CDU staff

2.20 Sterile instrument trolleys should be free of abrasions and be in good working order. Containers and trolleys should be easy to clean, properly maintained and should adequately isolate the goods in transit from environmental hazards[1].

2.21 In transit the contents of containers should be adequately identified by means, such as labels, which will not be erased in transit[1]. This is a CDU responsibility as per the example CDU/Theatre agreement in Appendix 1.

2.22 Vehicles reserved for the delivery of sterile packs/trays should be used[1]. If dedicated vehicles are not used then each vehicle used must be cleaned before use for the transport of sterile packs/trays.

Storage of sterile packs/trays

2.23 Entry to the sterile pack/tray storage areas should be restricted to authorised and trained personnel[1].

2.24 Movement of personnel within the area should be kept to the minimum necessary[1].

Things to consider:

Have a clear notice on the wall or storage system alerting staff to

handle the sterile packs/trays with care as example in Appendix 2.

2.25 Staff should perform hand hygiene before entering storage areas[1].

2.26 The sterile pack/tray storage facility should be secure, clean, dry and organised to aid stock rotation[1].

2.27 Storage should be segregated or, if it has to be shared, it should be with sterile equipment[1].

2.28 A high standard of cleanliness is required and packs must be kept well away from sinks and other sites of possible contamination[1].

2.29 The storage system must be well maintained as rough surfaces contacting the sterile pack/tray protective packaging may compromise the sterile pack/tray quality.

2.30 Sterile pack/trays should be stored safely in a manner which will assist in preserving the sterility of the contents and the stated shelf life[1].

2.31 Sterile pack/trays should be spaced on shelves with sufficient room to avoid friction or the jarring of adjacent products when one is removed[1] (see the product stored in the top shelf in Figure 2).

2.32 Sterile pack/trays should stored upright on shelves and **not** as the example of bad practice shown in Figure 3.

2.34 Sterile pack/trays should not be packed tightly together on shelves, as this may damage the packaging or may result in labels being pulled from the surface of the protective packaging.

2.35 The stacking of sterile packs/trays should only take place where it is defined in an agreement between CDU and theatres. See example in Appendix 1.

Figure 2: reducing the space between shelves reduces the potential stacking level but smaller sized sterile packs/trays should not be squeezed into the reduced space as seen in the top shelf.

2.36 Wrapped sterile packs/trays should not be dragged across shelving or racking and should not be lifted or pulled by their protective wrap.

Things to consider:

a) Review options to minimize or cease the stacking of wrapped sterile packs/trays.

b) Reduce the spacing between the shelves to reduce the stacking of product. See Figure 2.

Figure 3: example of a sterile pack/tray not being stored upright.

Avoid:

Placing of wrapped sterile packs/trays counter to the direction of the grid on open grid shelving as this may tear the wrap.

Placing of product on shelves in a manner that dislodges the label from the protective packaging of the sterile pack/tray - See Figure 2 showing dislodged product labels attached to the underside of one of the shelves.

2.37 Sterile packs/trays should be issued in rotation based on the first-in, first-out principle in accordance with a documented procedure[1].

2.38 Sterile packs/trays should be handled as little as possible[1]. The quantity stored should be limited to those actually needed within a reasonable time period[1].

Things to consider:

a) The provision of a computer in theatres stores to enable tracking of sterile packs/ trays into individual theatres. (This may bring benefits when a particular set that is only available in low volumes is required).

b) Have a contents list at the end of every shelf row.

2.39 Cleaning of all the storage environments holding sterile packs/trays should be in line with the National Cleaning Services Specification published by HFS. http://www.hfs.scot.nhs.uk

Handling of used instruments/trays/packs

For Theatre and CDU staff

2.40 All personnel who handle, collect and transport used instruments/trays/packs should be trained.

2.41 Where appropriate, personnel should wear protective clothing in accordance with local procedures. Consult the HPS National Infection Prevention and Control Manual[5]. http://www.hps.scot.nhs.uk

2.42 Many used instruments/trays/packs require careful handling as they contain expensive and delicate instruments[1]. Used instruments/trays/packs may also be heavy and contain sharp items.

2.43 Where untrained persons handle used instruments/trays/packs there should be an agreed protocol for alerting them that, if applicable, the used instruments/trays/packs are fragile and must be handled with care.

2.44 At the end of the surgical procedure theatre staff will carry out an instrument count, complete the tray check lists as appropriate and return the signed paperwork (possibly within a separate clear polythene bag) with the used instruments/trays /packs.

2.45 Instrument damage should be noted and reported.

2.46 There should be a quarantine procedure for surgical instruments used on definite or probable CJD patients. This should be agreed between CDU and theatres. Refer to example CDU/Theatre agreement in Appendix 1. This will include pre-cleaning of instruments where applicable.

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Storage of used instruments/trays/packs prior to dispatch

2.47 Used instruments/trays/packs being returned must be segregated from sterile packs/trays being delivered[1].

2.48 Used instruments/trays/packs should be stored in a dedicated area prior to dispatch.

2.49 "Single use devices should be disposed of at point of use and not be returned to the CDU. Screws, plates and implants should be purchased sterile single use."

2.50 "Contaminated instruments and equipment should be delivered to the CDU Contaminated Returns Lobby (in sealed containers conforming to UN3291" as stated in SHPN13 Part 1. See the example CDU/Theatre agreement in Appendix 1.

Things to consider:

a) Consider organised loading/configuring of used instruments/trays/packs into the transport carts as this will assist in faster processing time of the used instruments within the CDU.

b) The use of a wall notice similar to that in Appendix 2 to alert staff to handle used instruments/packs/trays with care.

2.51 Have clear instructions on the loading of used instruments/packs/trays into transport carts (see example CDU/Theatre agreement in Appendix 1).

2.52 Ensure the relevant paperwork is present and completed for each product.

Figure 4: example of bad practice in loading transport carts.

Avoid:

Disorganised loading/configuring of used instruments/packs/trays into the transport carts (see Figure 4) as this may delay the processing time on return to the CDU. It may also damage the used instruments.

Internal transport of used instruments/trays/packs

For Theatre and CDU staff

2.53 There should be documented procedures for collection of used instruments/packs/trays.

2.54 Used instruments/trays/packs returned must be segregated from sterile packs/trays being delivered[1]. Refer to the example CDU/Theatre agreement in Appendix 1.

Figure 5: example of vehicle for internal movement within theatres of used instruments/trays/packs from dirty utility to collections area within the theatre suite.

Appendix 1: Example of a CDU/Theatre agreement

A decontamination process is provided to (x)*: **insert as applicable*.

Specialities Supplied:

- Ophthalmology;
- Orthopaedics;
- General & Vascular;
- Gynaecology;
- Ear, Nose and Throat;
- Oral & Maxillo Facial;
- Anaesthetics;
- Urology.

The above specialities are supplied with comprehensive Edinburgh Trays, supplementary trays and packs and single use hollow ware.

Theatre trays

- where the instrument manufacturer's reprocessing instructions as EN 17664 specify pre cleaning at point of use (such as remove excess soil with a disposable cloth) this activity will be detailed in this agreement;
- all supplementary packs will be returned to CDU from the User Areas in polythene bags;
- all instruments are returned to their original tray and are packed in such a way as to avoid damage and contain contents for transportation;
- all supplementary instruments are returned in the transportation boxes provided and have an appropriate label attached. All priority supplementary instruments should be placed in a red priority box and all others in a blue box and sealed with black cable ties;
- all of these products may be fragile and should be handled with care at all times;
- all required documentation should be signed by theatre staff and returned to the CDU.

Master tray lists and identification of trays

- all trays must have an agreed tray list of contents prior to going into circulation. CDU hold master copies of all tray lists and a copy will be sent to the User Departments. Any tray changes must be agreed prior to their implementation on the specified documentation. The maximum product weight is (x)*kg;
- all trays are identified by a name label plus a white bar code label with a unique bar code number.

Delivery and uplift

- The CDU will deliver sterile packs/trays in transport carts/containers that provide suitable protection of the sterile pack/trays. Trays and packs are delivered and picked up 7 days a week at pre arranged times. All deliveries and uplifts are made to (x)*. (x)* will be delivered to Theatres (x)* times a day Monday to Friday and if required on a Saturday morning (all will be in locked trolleys). Urgent items outwith these times will be collected by either CDU or Taxi.

CDU opening times

- Monday – Thursday 8:00am – 09.30pm;
- Friday 8:00am – 09:00pm;
- Saturday 8:00am – 4:00pm;
- Sunday 8:00am – 4:00pm;
- Public Holiday Closure Christmas Day : New Years Day;
- Or otherwise negotiated with prior notice and funding.

Inspection of sterile product received from CDU

Sterile pack/tray product should be inspected on receipt at Theatres and confirmed as satisfactory. A timeline for reporting rejected sterile pack/tray product at this stage should be agreed. Clear responsibilities should be established between CDU and Theatres for sterile pack/trays that have been receipted as satisfactory in Theatre and at a later date are found to be of unsatisfactory quality prior to use. Unsatisfactory quality may include damaged protective packaging or missing labels.

Handling of sterile product delivered from CDU

Sterile product may be fragile and should be handled with care at all times.

Storage of sterile product delivered from CDU

Sterile pack/tray product will be stored in appropriate storage rooms or areas that maintain the required product quality over its shelf life. If stacking of wrapped sterile pack/tray product is agreed the conditions are required to be defined e.g. the maximum number of products to be stacked for a given product type. Any planned changes to storage conditions or product packaging systems should be agreed and confirmed as satisfactory prior to their introduction.

Turn around

- all packs will be returned to Theatres within 48 hours of their arrival in CDU;
- priority trays will be returned within 12 hours or on the next delivery;

- turn around is dependent on Tray needs being identified by users, staffing levels and all machinery operational in CDU;
- if trays are requested outwith the normal pickup and delivery times and CDU transport is unavailable, Trays will be returned to User Departments by way of a Taxi, whose fare will be charged to the User Department;
- a minimum of 4 hours is required for processing priorities with transport time in addition.

Points of contact

Provide the name and contact details, phone and email for those below.

- CDU Production Manager or Supervisor;
- Theatre Co-ordinator, Senior Team Leader or Team Leader in charge of the Theatre speciality.

Monitoring and quality

- for the purposes of monitoring the performance of this agreement, whether relating to quantity or quality, the managers signing this shall exercise responsibility and authority on behalf of the Theatres and CDU and will liaise directly with each other;
- the designated officers will regularly review performance operationally and agree and implement any change during the period of this agreement;
- quality is the joint responsibility of the Theatre and CDU and dialogue is encouraged to effect improvements to services;
- in addition, the Theatre or CDU has the right to undertake ad hoc studies and consumer surveys to assist the process of monitoring quality standards.

NHS Board - Signed on behalf of:

CDU _____

Print Name _____ Date _____

Signature _____ Date _____

Theatre _____

Print Name _____ Date _____

Signature _____ Date _____

Appendix 2: Example of handling precautions for sterile packs/trays

example of a precautionary notice.

Glossary

Aseptic presentation: introduction and transfer of a sterile product using conditions and procedures that exclude microbial contamination. [EN 11607-1:2014][4]

CE marking is a declaration by the manufacturer that their product is compliant with EU legislation.

Central Decontamination Unit: A Central Decontamination Unit (CDU) is characterized by the following features- it operates with appropriately segregated decontamination processes and effective environmental control to protect both staff and product. The CDU operates in compliance with the Quality Management System EN 13485 and the Medical Device Regulations. It has dedicated management and operational staff. The unit can supply third party legal entities.

Decontamination: A combination of processes, including cleaning, disinfection and/or sterilization, used to render a reusable item safe for further use.

Edinburgh Tray system: a wrapped set of instruments organised within in a porous tray.

Fragile: easily broken, damaged or harmed – harmed when stressed.

Mechanical shock: sudden movement of the product caused by for example dragging or dropping.

Packaging system: combination of the sterile barrier system and protective packaging. [EN 11607-1:2014] [4]

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. [EN 11607-1:2014] [4]

Sterile barrier system: minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use. [EN 11607-1:2014] [4]

References

Note: These references were current at the time this document was produced. Anyone using this publication should ensure that they refer to the current version of any reference.

1. Scottish Health Technical Memorandum SHTM 2010 Part 5 – section C9 published by HFS 2001.
2. Standards and Recommendations for Safe Perioperative Practice Third Edition. Association of Perioperative Practice 2011 section 8.7 Use and handling of surgical instruments.
3. Standards and Recommendations for Safe Perioperative Practice Third Edition. Association of Perioperative Practice 2011 section 5.5 Aseptic technique.
4. Packaging for terminally sterilized medical devices EN 11607-1: 2014 published by CEN.
5. National Infection Prevention and Control Manual published by Health Protection Scotland 2014.

Associated Publication

Theatre and CDU Guidance – Management of reusable surgical instruments during transportation, storage and after clinical use – GUID 5010 Part A – design advice note for planning published by Health Facilities Scotland 2014.