

Theatres and CDU Guidance

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

Part A – design advice note for planning

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Executive summary

Nationally approximately 56 million reusable medical devices are reprocessed in Central Decontamination Units (CDU) annually*. In some boards CDUs provide a sterile service to one or two theatres while other boards provide a service to almost one hundred theatres. This CDU sterile service produces sterile packs/trays comprising of variable numbers of surgical instruments contained in a variety of packaging such as sterilization wrap, reusable containers, preformed rigid trays, flexible peel pouches, sterilization bags and header bags. These sterile packs/trays are of variable weight and dimension.

This guidance has been developed based on a stakeholder approved brief that highlighted concerns over management of surgical instruments before and after decontamination and the need for clear guidance.

The guidance is presented over two separate documents. This document GUID 5010 Part A provides design advice for the planning of new build or the refurbishment of existing storage facilities for sterile pack/trays. This advice is intended for designers, estates and clinical staff involved in planning.

The second document GUID 5010 Part B presents the operational guidance. This describes the handling, transport and storage of sterile packs/trays and the handling, storage and transport of used instruments/trays/packs. It is intended for theatre managers, stores personnel, theatre staff and porters.

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.

The 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 the operational 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.

*CDU Contingency Planning Status 2012 Report, HFS 2013.

1. Introduction

- 1.1 The CDU Contingency Planning Status 2012 Report published by Health Facilities Scotland (HFS) in 2013 indicated that nationally approximately 56 million reusable medical devices were reprocessed in CDUs over the year. These medical devices included tissue forceps, needle holders, scissors, retractors, biopsy needles, suction tubes and a huge range of miscellaneous instruments. In some boards CDUs were required to provide a sterile service to one or two theatres while other boards provided a service to almost one hundred theatres. Specialities supplied included Ophthalmology, Orthopaedics, General & Vascular Gynaecology, Ear, Nose and Throat, Oral & Maxillo Facial, Anaesthetics and Urology.

A 2012 National Services Scotland (NSS) report of a visit to a Hospital's orthopaedic theatres stated there were "concerns over excessive handling, stacking and poor storage conditions for trays which are prone to damage". Consultation feedback during development of this guidance supported the view that inadequate sterile pack/tray storage space including insufficient space between storage shelves resulted in non-conforming sterile packs/trays and impacted adversely on theatre lists.

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.

Purpose/ Scope

- 1.2 The GUID 5010 guidance comprising of two documents covers design and operational guidance.

Part A the 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.

Part B 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).

- 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 Design advice note for planning

Theatres – storage of sterile packs/trays

- 2.1 Sterile packs/trays supplied from a Central Decontamination Unit (CDU) may be stored in several locations in a theatre suite such as a bulk store room, local store rooms and a local store area adjacent to the theatre preparation room.
- 2.2 There should be dedicated storage for the sterile packs/trays. For new builds and where possible for refurbishments the storage of sterile packs/trays supplied from a CDU should be in a dedicated room.

Function

- to enable the secure storage of sterile packs/trays in clean, dry, dust free, sunlight protected conditions that will maintain/protect the product quality over its shelf life which may be of the order of one year. This includes the protection of the product's sterile barrier;
 - to enable the sterile packs/trays to be readily accessible when it is required for use;
 - to enable minimum handling and disruption to remaining stock items when the required processed product is removed from storage;
 - to enable appropriate stock control activity over all areas and allow first-in, first-out principles to be followed.
- 2.3 A range of specialities may require to be provided for in storage rooms. Specialities for example may include Ophthalmology; Orthopaedics; General & Vascular, Gynaecology; Ear, Nose and Throat; Oral & Maxillo Facial; Anaesthetics and Urology. A bulk store may hold a mix of sterile packs/trays to supply these specialities with a local store room holding sterile packs/trays for a single speciality.

Activity

- 2.4 Activities include the following:
- Unloading of sterile packs/trays from transport carts or transport boxes into dedicated storage locations;
 - stock control administration;
 - removal of sterile packs/trays from storage;
 - loading of sterile packs/trays onto trolleys to transport to other areas for clinical use or to other storage areas. Note some internal transport trolleys will be loaded with multiple sterile packs/trays which may have a combined mass that presents a challenge for some staff to manoeuvre.

Occupancy

Design Notes.

- 2.5 For planning purposes a layout drawing showing sterile packs/trays movement from receipt at theatres reception to delivery into the theatre preparation room should be produced. Any temporary storage locations should be included in the planning process, e.g. dedicated shelving outside a preparation room. This exercise should identify all surfaces and environments that sterile packs/trays will encounter prior to use and verify that these will maintain the required product quality of the sterile packs/trays. Planning should also include details of the number of staff planned to work in each storage room, the sterile packs/trays storage system(s) and any other items (with their dimensions) of equipment/furniture/fitting. Refer to [Table a](#) – specification of storage room finishes and [Table b](#) – list of equipment/furniture/ fittings when considering these matters. This planning exercise should determine whether a single door or double door is required to accommodate the planned activity.

Consideration should also be given to the use of an electronic system to track sterile packs/trays and used instruments/trays/packs within theatres. Consider having this system able to communicate with the tracking system in use in the CDU.

The quality of some sterile packs/trays may be fragile to mechanical shock and should therefore be handled with care. Most sterile packs/trays require to be handled and stored in a manner that keeps them upright at all times. An example of a wall notice advising of the need to handle with care is given in [Appendix 1](#).

A key factor in maintaining the quality of the sterile packs/trays is to ensure that all surfaces that come into contact with them have a high quality of surface finish i.e. clean, smooth and free from any abrasive or sharp protrusions.

Selecting storage systems

- 2.6 Sterile packs/trays from the CDU comprises a range of medical devices that may include tray sets, soft packs, instrument packs, ward packs and singles (single instruments). The protective packaging can include wraps, re-usable containers, pouches and bags. These sterile packs/trays are of variable size, shape, weigh and construction. Presently, heavy tray sets can be of the order of 12 kg in mass. These sterile packs/trays may require lifting equipment to aid movement. Some sterile packs/trays can have their protective packaging (and sterile barrier) damaged if moved over an abrasive storage surface.

In order that a suitable sterile packs/trays storage system is specified the mix of product intended to be stored has to be defined with clear details of the product type, weight and dimensions.

- 2.7 For sterile packs/trays protected by wrap, pouches or bags, a clear agreement between CDU and theatres management as to the suitable storage

configuration is required. For example whether or not wrapped product can be stacked and if stacking is permitted what the limitations are. It should also be confirmed whether wrapped product is supplied with an external tray base and whether this is plastic or metal. Sterile packs/trays produced with an external tray base (as shown in [Figures 2 & 6](#)) may be abrasive to the surface finish of a metal storage shelf when sterile packs/trays are placed onto or when being removed from a shelf. For pouched and bagged sterile packs/trays consider whether storage bins are required on the storage shelves.

- 2.8 For re-usable containers it is normal practice that only those of the same provenance may be stacked together. A layout drawing defining the sterile packs/trays to be stored on each shelf will assist in the planning process. Consideration of future storage needs should be addressed and this may affect the selection of the type of storage system. Some modular storage systems can be easily reconfigured without disruption to the building fabric. Stored sterile packs/trays should be contained within a shelf or racking without projecting beyond the front edge. Designers should be aware that some sterile packs/trays are greater than 600mm long which may be the maximum shelf depth for some storage systems. The maximum load and capacity for each shelf should be defined. Where heavier sterile packs/trays are to be stored the Manual Handling regulations may require these items to be located at a height where safe handling is possible such as mid height shelves.
- 2.9 Sterile packs/trays should be stored in an organised manner that allows each product label to be read without handling the sterile packs/trays. Note: currently some sterile packs/trays are labelled on their top surface and other sterile packs/trays are labelled on a front surface. It is noted that with items packed in pouches or paper bags it will not be likely to be able to view each label without handling the product. Sterile packs/trays should not be stored on the floor.
- 2.10 When considering storage systems, determine whether free unobstructed access is required from both sides of the storage system and the type of labelling to be attached to the shelves. The height, width, depth, number of shelves and number of bays or compartments of the storage system should be defined. A design rationale should be in place stating the capacity requirements of each sterile pack/tray storage area. The quality of finish of the storage system surface which contacts the sterile packs/trays can have a significant negative impact on certain protective packaging systems. Some sterile packs/trays that are wrapped, pouched or bagged can be compromised by contact with rough surfaces. Therefore shelf or wire rack systems should have smooth surfaces and be of a material that remains in this state.
- 2.11 Epoxy coated stainless steel or electro polished stainless steel are examples of suitable finishes for shelves or racking. Shelves can be supplied as an open grid ([Figure 1](#)) or be a solid surface ([Figure 2](#)). Open grid shelves can be supplied with additional shelf dividers if required to provide better stock management. Specify whether the shelf posts are required to be bolted to the floor or be supplied with adjustable feet to compensate for an uneven floor. Specify whether the storage system requires to have adjustable shelves if applicable. Some modular storage systems are easily expandable and can be configured end to end, at right angles or in a “T” shape arrangement. The lower

shelf of a storage system should be a nominal minimum of 150mm above floor height. It may be appropriate to have the lowest shelf as a solid surface to prevent splash back onto product during cleaning of the floor. The top shelf should be a nominal maximum height of 1350mm above floor level where heavy product is required to be stored. This is to enable full forward reach onto the shelf as HBN 00-03 published in 2013. In order that product quality is maintained sterile packs/trays require to be lifted (and not dragged) onto or from a storage shelf. Spacing between storage bays should be sufficient to accommodate the use of sterile packs/trays lifting equipment where required. The initial sizing of the storage system should be informed by the user defining the amount, type and weight of product to be stored and whether spare capacity is required to be built in.

- 2.12 Mailbox type storage systems (that provide an individual storage space for sterile packs/trays with no stacking as seen in [Figure 3](#) for storage of wrapped sterile packs/trays will offer good product protection and visibility of product information. Some systems make use of a carrier basket for individual sterile packs/trays (see [Figure 4](#)). These can also be used in moving sterile packs/trays (with no stacking) from storage into transport carts as seen in [Figure 5](#). There are modular storage systems that allow easy adjustment such as shelf spacing or additional bays that may be a good investment where new specialities and or new waiting list initiatives put pressure on storage capacity.
- 2.13 For interim solutions where existing storage conditions have multiple stacked sterile packs/trays - The introduction of additional shelves by reducing the shelf spacing will decrease the load on (compression of) individual sterile packs/trays and improve the storage conditions providing the sterile packs/trays are not subsequently squeezed together into the resulting reduced space.

Room M&E

- 2.14 Storage room M&E requirements include a temperature of 16-21⁰C, relative humidity 30-60%RH, positive pressure with respect to the corridor, filtration F5 (as EN779), light levels of 300 Lux and protection from direct sunlight and water.

Room finishes

2.15

Wall	Wall Finish	Surface Finish (SHTM 56): Performance category 5. Recommended acrylic paint.
Floor	Floor Finish	Surface Finish (SHTM 61): Choice of floor finish is based on a risk assessment.
Ceiling	Ceiling Finish	Surface Finish (SHTM 60): Performance category 3.
Doorset	Doorsets	(SHTM 58) Compliant. Consider the need for a glazed panel.
Window	Windows Type	(SHTM 55) Not essential. If provided sunlight protection of stored product is required.
Internal glazing	Glazing	(SHTM 57) Clear, (for observation from adjacent work areas).
Ceiling Hatch	Hatch	If required to allow access to services above, the hatch must be capable of being sealed after use and be compatible with the ceiling finish.
Finish Notes	Heavy duty protection (as SHTM 69) should be considered, i.e. a mid height crash rail (taking account of the dimensions of the transports carts), durable materials on the lower part of walls, protective corners and splayed skirting. Door protection should include protective plates and buffer rails mounted vertically at door edges. Floor finish together with the sub floor should allow for the heavy traffic (maximum trolley weight specified) in this area. Edges where the wall meets the ceiling should be coved.	

Table a: specification of storage room finishes.

Room equipment/furniture/fittings

2.16

Storage system for sterile packs/trays from CDU. (see wall notice in appendix 1)
Transport carts.
Transport containers.
Fire alarm.
Lifting equipment for heavy sterile packs/trays
Foot stool
Fire extinguishers.
Clock battery operated and wall mounted.
Security Alarm with push button and wall mounted.
Desk/Chair.
Filing cabinet.
Computer.
Data scanner/Telephone.
Socket double outlet computer data, Socket outlet telephone, wall mounted.
Socket outlet intercom, wall mounted.
Socket outlet switched 13 Amp double, ac and wall mounted.
Socket outlet switched 13 Amp single, ac and wall mounted.

Table b: list of equipment/furniture/fittings to consider.



Figure 1: mix of wrapped, pouched and containerised sterile packs/trays on open grid epoxy coated steel shelving of 600mm width.



Figure 2: sterile packs/trays, with some held on external plastic tray bases, being stored individually on solid shelves.



Figure 3: system storing individual sterile packs/trays.



Figure 4: carrier basket with silicon liner for individual sterile packs/trays.



Figure 5: example of an external transport system used to contain individual sterile pack/trays in carrier baskets (as Figure 4).



Figure 6: reducing the space between shelves reduces the potential stacking level

Appendix 1: Example of handling precautions for sterile packs/trays

FRAGILE



HANDLE WITH CARE

**KEEP containers and
wrapped instrument sets
UPRIGHT**

Stacking may damage product.

Glossary

AE(D) The Authorising Engineer (Decontamination) is an independent professional adviser to the healthcare organisation.

Antifragile: improves when stressed as applied to a system.

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

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.

Creutzfeldt-Jakob disease (CJD) is a rare and fatal condition that affects the brain.

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.

Medical device: Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer, to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; and control of conception: and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (Source: EU Council Directive 93/42/EEC).

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

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]

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]

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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.

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