Safety Action Notice

Reference: SAN2306 **Issued:** 24 November 2023 **Review Date:** 24 November 2024

Medical devices intended for use in a sterile state: review of systems and procedures

Summary

Medical devices intended for use in a sterile state can introduce risks of infection if they are supplied or used in an unsterile state. Systems and procedures should be reviewed to ensure patient safety. Steps need to be taken to prevent misuse of medical devices such as surgical instruments and implants, intended to be used 'sterile'. It is important to maintain the sterility of the devices up to the point of use, and to perform the necessary checks before use on patients.

Action

1. Bring this notice to the attention of all appropriate management and staff

   Purchasing / procurement / storage of single use sterile medical **devices including implants**

2. Procurement policy and systems should be reviewed to ensure only sterile devices are specified when raising a purchase order.

3. Develop, implement and periodically review a Standard Operating Procedure (SOP) for the receipt of sterile devices to ensure:
   a. the delivery note details match the purchase order including the sterility status i.e. labelled STERILE
   b. the label on the device states STERILE, there is a UKCA mark and a single use symbol (below),
   c. the device is within its expiry date
   d. the packaging is in an acceptable condition (dry, intact, no sign of damage)

   Note: devices that fail any of the above criteria should be removed from use, quarantined, and reported / returned to the supplier.

4. Store sterile devices in an area dedicated for storage of sterile devices (refer to guidance GUID 5010 Part A - Design advice note for planning). Do not allow non-sterile devices to be stored in the same area

5. Implement 'first-in-first-out' stock management systems with periodic compliance checks to ensure sterile devices are stored and transported appropriately and expiry dates are monitored. Refer to the guidance GUID 5010 Part B - Operational guidance: Theatres and CDU Guidance Management of reusable surgical instruments during transportation, storage and after clinical use.

6. Ensure all procurement and store staff are trained on their role in the SOP and the identification and meaning of label, content and symbols on sterile device packaging.

7. Incidents involving unsterile medical devices intended for use in a sterile state should be reported locally (e.g. Ulysses, InPhase, Datix) and to IRIC (Report an incident)

Decontamination of reusable surgical instruments

8. Reprocess the reusable surgical instruments in accordance with the process described in the Quality Management System (QMS), taking account of manufacturer instructions and validation data.

9. Regularly maintain and check reusable containers including filters, seals, lids and other components before each use, in accordance with manufacturer instructions. Reusable containers should be decontaminated after each use in accordance with QMS.

10. Before dispatch of each sterile item, verify that:

    a. the items have been subjected to all required decontamination steps as per QMS,
    b. all steps are tracked and recorded,
    c. chemical indicator and biological indicator (if used) changed colours/passed
    d. packaging and label are intact
    e. accompanied with dispatch note.

Checks prior to clinical use

11. Before use on patients, sterile devices must be checked to ensure:

    a. The item is labelled as **STERILE** (Figure1);
    b. For sterile reusable devices, chemical indicator (if used, consult your Central Decontamination Unit provider) has changed colour to indicate the devices have been subjected to sterilization process;
    c. the sterility expiry date (Figure 2) has not elapsed;
    d. the sterile packaging/container and all components are intact, and the seal is not compromised. Consult Central Decontamination Unit provider or manufacturer if there is any doubt.
    e. appropriate quality and condition of the device (clean, dry, function properly, no sign of defect or surface damage such as corrosion).

Equipment details

Surgical instruments and implants intended to be used as sterile devices

Figure 1. Sterile symbol

Figure 2. Sterility expiry date symbol

Background

This notice is issued to raise awareness of the risks of unsterile implants and devices, and to provide guidance on suitable procurement, management and use procedures for to prevent unsterile devices inadvertently being used on patients. The notice also raises awareness of the World Health Organisation (WHO) surgical safety checklist related to sterility of devices. Tool and Resources (who.int)

Suggested onward distribution

Central Decontamination Units
Community Dental Officers
Day Surgery
Decontamination Leads
Dental Hospitals
Device Managers
Endoscopy
General Dental Practitioners
General Medical Practitioners
Health Centres
Health & Safety
Infection control
Local Decontamination Units
Microbiology
Operating Departments
Operating Department Practitioners
Orthopaedics
Pharmacy
Risk Management
Sterile Supplies Departments
Sterile Services Departments
Supplies/Procurement

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

Report an incident: Information on how to report an adverse incident

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service https://www.nss.nhs.scot/