Trust Policy

Worcestershire Acute Hospitals NHS Trust

Decontamination of Medical Devices Policy

Department / Service:	Sterile Services & Infection Prevention Team
Originator:	Tracey Cooper, Director of Infection Prevention & Control
Accountable Director:	Paul Brennan, Chief Operating Officer
Approved by:	Infection Prevention & Control Steering Group Trust Management Executive
Date of approval:	3rd February 2022 (IPCSG) 14th December 2022 (TME)
Review Date: **This is the most current document and should be used until a revised version is in place**	24th February 2026
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments	All clinical areas
Target staff categories	All staff

Policy Overview:

This policy sets out the principles and standards for the decontamination of medical devices, in order to ensure patients and staff are protected from risks of cross-infection due to medical devices.

It replaces WAHT-INF-009 General Decontamination Protocol, and WAHT-INF-037 Decontamination Policy.

Key amendments to this Document:

Date	Amendment	By:
24-05-22	New document approved Addition to Sections 9 and 14, to specify the action to be taken when correct process is not followed prior to transport of a device. Addition to Section 16 to clarify that monitoring arrangements for the local policies and SOPs which will be produced based upon the principles set out in this document will be set out in those documents, as arrangements will vary.	Tracey Cooper, DIPC
25-11-22	Addition of Permit to Work template (Appendix B). Section 14.3 - Clarification from AP(D) of which sections of Appendix B are to be completed by Designated User, Competent Person and Authorised person	Julie Booth, Deputy DIPC

	Addition of items 4.10 & 14.5 – Confirmation from AP(D) of arrangements for equipment with blood/ internal fluid ingress before sending to Technical Services/Siemens and equipment deemed contaminated beyond economical repair.	
24th November 2025	Document extended for 3 months to allow time for review and update	Angela Roxburgh-Powell

1.0 Introduction

Medical devices and items of equipment that are used on more than one patient may transmit infection between patients. All such devices must be adequately decontaminated between each patient use to ensure patient safety.

Each Sterile Service department within WAHT is registered with the Medicines and Healthcare Products Regulatory Agency (MHRA).This UK mandatory requirement. To enable this registration the following certification is in place within each sterile service department – Article 12 of Directive 93/42/EEC, ISO 13485:2016.

All other devices which cannot be centrally decontaminated within sterile service departments must be decontaminated in accordance with manufacturer's decontamination instructions and any other applicable guidance. This includes the decontamination of flexible endoscopes and nasoendoscopes (NAS Scopes).

It also includes 'All products except medicines, used in healthcare for the diagnosis, prevention, monitoring and treatment of illness or disability. The range of products is wide and ranges from relatively low risk to extremely high risk devices' (MHRA) Managing Medical Devices April 2014.

2.0 Purpose

This policy sets out the principles and standards for the decontamination of medical devices, in order to ensure patients and staff are protected from risks of cross-infection due to medical devices.

3.0 Scope

This procedure applies and is applicable to all procedures in which a medical device or item may be used. It is the responsibility of staff within the Trust to ensure the use of medical devices is in line with this document and manufacturers guidance.

A large number of departments and services are involved in the decontamination of medical devices and their handling. The principles in the policy must be applied to the range of local policies and standard operating procedures produced by those services and departments.

4.0 Key Principles

4.1 Purchase of reusable medical devices and equipment must include, prior to the purchase, an assessment of the processes recommended for decontamination and the ability of The Trust of meeting those requirements. This applies to all medical devices and items and not only those which are returned to a sterile services or endoscopy departments for reprocessing. Centrally processed items are typically those which come into contact and go into bodily cavities and any associated items of auxiliary equipment which are used in conjunction with them.

4.2 Awareness of hazards associated with decontamination, and ensuring all employees are provided with appropriate protective equipment and working facilities.

4.3 Ensuring all relevant Trust employees are trained in the correct decontamination procedures, use of approved equipment, devices and reagents associated with the decontamination process. This includes ensuring staff are fully aware and conversant with other related safety factors according to relevant recommendations, guidance and regulatory requirements.

4.4 Equipment and medical devices must be maintained and decontaminated in accordance with manufacturer's guidance and the detail within this document at all times.

4.5 Equipment and devices are always decontaminated between patients, and before transporting equipment or devices to another ward, department or for maintenance. This ensures the item is in a safe state for handling or for use, and minimises the potential risk of cross infection.

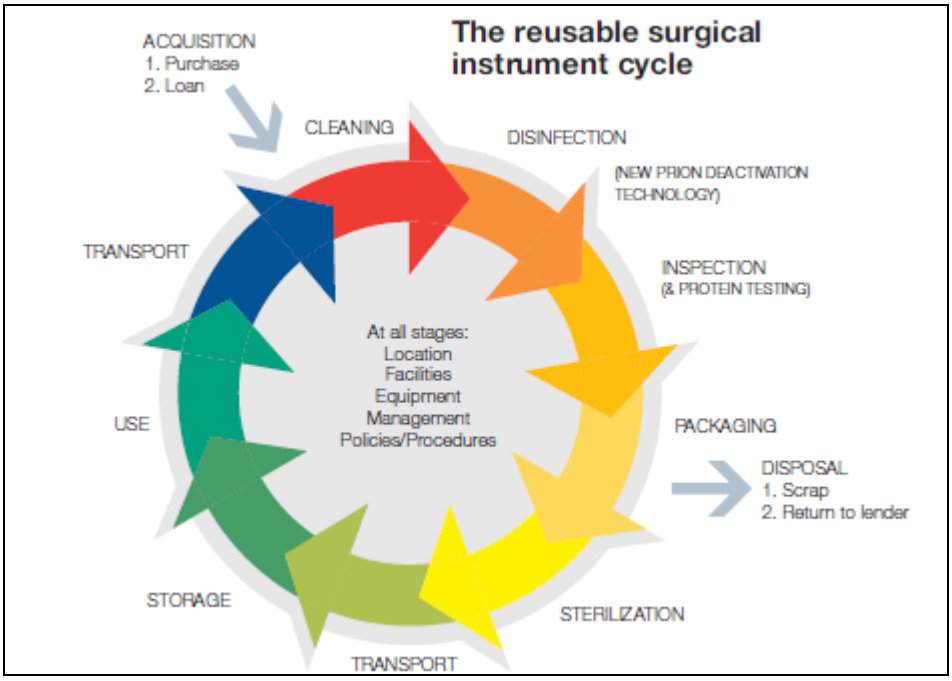
4.6 Where appropriate and where it is required, ensure that any required documentation relating to the decontamination of any item is kept and maintained in accordance with any recommendations, guidance and regulatory requirements and in accordance with the specific requirements of the related department.

4.7 Medical Devices and items sent to sterile service departments will be processed in accordance with the requirements of the SSD Quality System and following the approved standards in place within those departments. All other devices which cannot be processed centrally within sterile service departments will be decontaminated in accordance with manufacturers device specific decontamination instructions, or any other relevant local Standard Operating Procedures (SOP's) or protocols in place. This includes the decontamination of flexible endoscopes and nasoendoscopes (NAS).

4.8 Where applicable and dependant on the nature of the device being decontaminated facilities will be compliant with applicable Health Technical Memorandum (HTM) and/or any other related requirements.

4.9 All relevant elements of the reusable surgical instrument cycle should be in place for each item that is decontaminated for reuse, in line with HTM 01-01. It is however recognised that not all elements will apply to all items, particularly low risk items which only require manual cleaning.

4.10 Any equipment that cannot be cleaned and decontaminated due to blood /fluid ingress must be bagged and clearly labelled **'Equipment Internally Contaminated'**, prior to sending to Technical Service /Siemens.



5.0 Roles and Responsibilities

5.1 Decontamination Duty Holders

The Chief Operating Officer is the nominated Decontamination Lead for the Trust.

In line with HTM 01-01, the Trust has in place a range of required duty holders who undertake the roles as described in HTM 01-01. The list is updated from time to time and is available on the intranet, and from the DIPC.

5.2 Managers of departments and wards using medical devices

- These managers are designated as leads for ensuring the correct cleaning and decontamination of the medical devices and equipment in use in their area is undertaken.
- They must also ensure all equipment in use is fit for purpose at the point of use and where applicable the relevant servicing and maintenance takes place in line with manufacturers regulatory, non regulatory and local requirements.
- Appropriate action must take place if equipment fails.

- Servicing, maintenance and testing requirements must be managed monitored and maintained. This includes thorough cleaning and then completion of a 'decontamination of equipment certificate' prior to sending an item for servicing or repair.

- Ensuring all staff who clean or decontaminate medical devices have been trained to an appropriate standard and that this is recorded. Be aware of legal requirements and monitor practice to ensure it is in accordance with the processes.

- Refresher training must be completed on a regular basis and documented, in accordance with the system in place. Training once provided must be recorded in accordance with the system in place. This must be monitored by line manager of the employee.

- The training requirements within Sterile Service departments will also be maintained in accordance with the requirements of the Quality Management System (QMS) in place.

- Ensuring medical devices and equipment in their areas are decontaminated between patients using the agreed method so that equipment is safe for reuse on other patients. Auxiliary equipment such as drip stands and monitors must be decontaminated during the time in ongoing use in accordance with the cleaning schedules in place.

- Ensuring there is sufficient equipment to allow for continued service provision, taking into account the turn-around time required for instrumentation/devices reprocessed within sterile services, central reprocessing units or other areas used for decontamination.

- Ensuring risk assessments are documented, fed into the relevant groups and risk registers.

5.3 Advice and support on decontamination issues is available via Sterile Services, the Infection Prevention Team and Consultant Medical Microbiologists, the Trust Authorised Person (Decontamination), and the Authorising Engineer (Decontamination) in accordance with the nature of the issue.

6.0 Definitions

Medical Devices refer to all products, except medicines, used in health care for diagnosis, prevention, monitoring or treatment of medical conditions. The range of products is very wide. It includes contact lenses, heart valves and hospital beds, resuscitators and radiotherapy machines; surgical instruments and syringes; wheelchairs and walking frames. Other auxiliary supporting devices or items include electrical devices and monitoring screens. This list is not include every item and applies to any item which is subject to contamination during its use.

Medical devices are designated either as single-use, single patient-use or reusable. The following definitions apply:

6.1 Single-use A device that is used once, on a single patient, and then disposed of.

6.2 Single Patient-Use A device that can be used more than once on a single patient, and can be decontaminated between uses on that patient only.

6.3 Reusable A device that can be reused on multiple patients' provided it is adequately decontaminated between uses.

Single use items cannot be reprocessed under any circumstances by any of the sterile service departments within WAHT. These items must be disposed of at point of use. Some department use a mixture of single use items with reusable items – extreme care should be taken in such departments to ensure that the single use item is discarded after use and the reusable item is returned as a supplementary item or part of a tray system to the central processing sterile services department.

Single-Use Items

The expression "**Single Use**"* on the packaging of medical devices is a legal term meaning that the manufacturer has instructed:

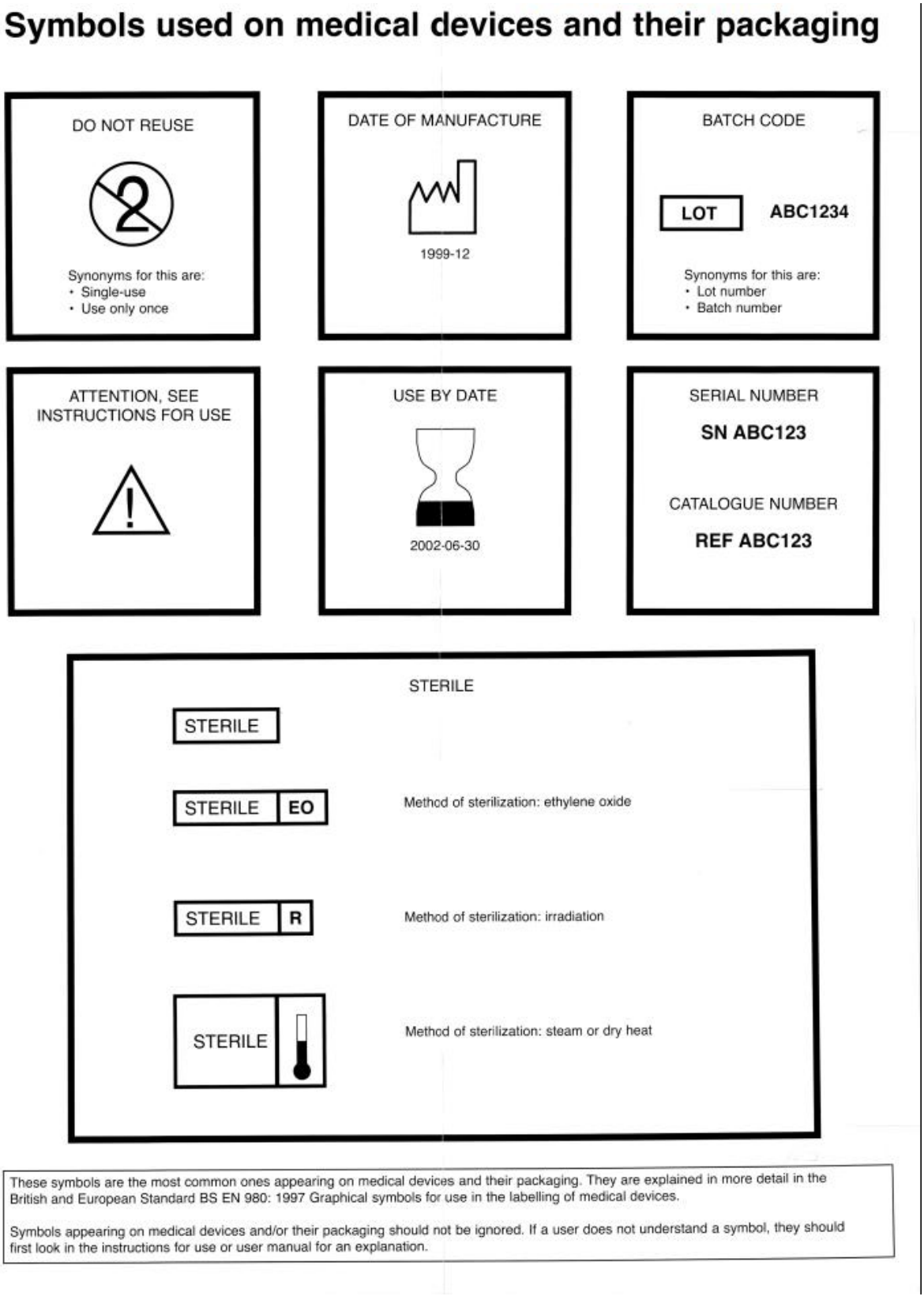
- the item is to be used once then discarded;

AND

- considers that the items are not suitable for use on more than one occasion.

* As an alternative to the expression "single use", other statements may be used, these include "Do not re-use", or a symbol comprising of the figure 2 with a diagonal line drawn through it (see below) which may appear on packaging.

BSYMBOLS USED ON MEDICAL DEVICES AND THEIR PACKAGING



Decontamination Processes

Decontamination can be the combination of processes, including cleaning, disinfection and sterilisation. Instrumentation and other medial devices or items which cannot withstand the sterilisation process are either cleaned or cleaned and disinfected in accordance with the protocols or SOP'S in place relevant to those items.

6.4 Cleaning is a process that physically removes visible contamination and many micro-organisms by using detergent, but does not necessarily destroy the micro-organisms. This includes blood, faeces, mucus, any bodily fluids or other physical contamination including bone matter in the case of surgical instrumentation.

Detergents are used in the cleaning phase to remove physical contamination but do not act as a disinfectant. Cleaning is an essential pre-requisite prior to any further decontamination process. If physical soiling is not removed subsequent disinfection or sterilisation may be ineffective.

Cleaning can be achieved by manual or automated processes but cleaning temperatures should be at or below 35°C. Temperatures above this will cause the fixing of any proteins present on the devices, making them more difficult to remove. Physical soiling should be removed as soon as possible after device use to minimise the challenge to any cleaning or disinfection process from dried protein residues.

6.5 Disinfection is a process that reduces the number of viable micro-organisms but may not inactivate some microbes such as certain viruses and bacterial spores. There are 2 main methods of disinfection:

Thermal disinfection: This is achieved by the device being subject to moist heat, usually at a temperature of above 90°C for a period of at least 1 minute: for example a bedpan washer, kitchen dishwasher.

Chemical disinfection: This is achieved by using effective disinfectant chemicals with appropriate dosing and ensuring an effective contact time is achieved, as recommended by the manufacturers of the disinfecting chemical or agent: for example endoscope washers achieve high-level disinfection using chemicals, low level disinfection of items can be achieved using disinfectant wipes.

6.6 Sterilisation is a process that removes or destroys all micro-organisms, including spores. The only sterilisation process in place within the Trust is steam sterilisation in a vacuum autoclave/ steriliser. These machines achieve specific temperature, time and pressure parameters to achieve sterilisation.

Some heat-labile items are damaged by heat, such as flexible endoscopes. They cannot be reprocessed via autoclave methods.

Sterilisation will not eliminate or deactivate prions, the cause of Creutzfeldt-Jakob Disease (CJD), which are resistant to conventional chemical and physical decontamination methods. Prions are not significantly inactivated by high level disinfectants or standard autoclaving. They

are extremely resistant to high doses of ionising and ultraviolet irradiation and are capable of surviving for long periods in the environment. Therefore effective cleaning is the essential process to reduce risk of CJD and other prion diseases.

Please refer to the latest Advisory Committee on Dangerous Pathogens (ACDP) and UK Government CJD/TSE guidance for detail of handling of surgical instruments and devices on known or suspected patients with CJD.

7.0 Classification of Infection Risk and Method of Decontamination

All items should be placed in one of the following categories to identify the appropriate level of decontamination needed to protect the patients / clients and staff.

Risk	Application of item	Recommendation
High	• In close contact with broken skin or broken mucous membrane. • Introduced into sterile body areas.	Cleaning followed by sterilisation.
Medium	• In contact with mucous membranes. • Contaminated with particularly virulent or readily transmissible organisms. • Before use on immunocompromised patients.	Cleaning followed by sterilisation or disinfection. NB: Where sterilisation will damage equipment, cleaning followed by high level disinfection may be used as an alternative
Low	• In contact with healthy skin. • Not in contact with patient.	Cleaning.

7.1 The decision on what action is taken to clean, disinfect or sterilise equipment depends on the risk of transmission of infection, and patient risk factors. Where the risk is high it may be more appropriate to use single-use disposable equipment, providing they are of equivalent quality to reusable instruments.

Factors also to be considered when choosing a method of decontamination include the nature of the contamination, the time required for processing, the heat, pressure, moisture and chemical/detergent pH Level tolerance of the item, the availability of the processing equipment and the quality and the risks associated with the decontamination method.

7.2 Sterile Services Departments (SSDs) accredited by a Notified Body must be used for the decontamination of all items requiring sterilisation. There must be a written Service Level Agreement (SLA) regarding the items to be sterilised and where appropriate any costs involved. Additional services which are required must be negotiated and agreed fully with the Manager of the department of processing prior to the commencement of reprocessing. All of the requirements of the Quality Management Systems (QMS) in place must be adhered to and the

local department processes followed of which the local departmental Sterile Services Manager will be able to clarify. The detail of this will also be included within the SLA in place. If rapid turnaround of surgical instruments is requested by the customer, the sterile services department management team is required to ensure the decontamination process in place is carried out safely and effectively and in compliance with legislation and standards. This can only be achieved if specified at the time of the request.

7.3 The decontamination method advised by the manufacturers reprocessing/cleaning instructions, guidance and regulatory requirements should be followed. Using any other process will invalidate warranties and transfer liability from the manufacturer to the person using or authorising the process. Additionally, there may be the potential of patient safety being compromised due to the potential effect of inappropriate/invalidated process being used. If there are any doubts about the manufacturer's recommendations, seek further advice.

7.4 When cleaning medium or high risk instruments/ equipment using the manual method, a sink which is deep enough to completely immerse the items to be cleaned must be used. All precautions must be taken to prevent splash and injury, by the correct use of appropriate personal protective equipment. Scrubbing of items can generate aerosols which may convey infective agents, therefore if scrubbing is necessary it must be carried out with the brush and item held beneath the surface of the water (immersion method). This method is not suitable or necessary for many items of equipment, i.e. electrical or large pieces of equipment and advice should be sought from their manufacturer.

7.6 Single-use brushes and single-use non-shedding cloths rather than re-usable items are to be used wherever possible. Any cloths or items which are not single use must be managed in to ensure cross contamination does not take place and also the multiplication of potentially harmful bacteria does not occur. All non single use brushes and cloths must be managed in accordance with the local cleaning and storage instructions. The disposal of any items must take place in accordance with the waste management policy in place within the Trust.

7.7 If disinfection is required, the method recommended by the manufacturer must be used.

Environmental Disinfectants

Environmental disinfectants can be used for a wide range of tasks including:-

- Rapid disinfection of equipment and surfaces.
- Treatment of spillages of potentially hazardous matter, (wear gloves and apron).
- Disinfection of re-usable items of equipment that are heat labile.
- Cleaning during outbreaks on the advice of the Infection Prevention Team.

The properties of disinfectants vary from one product to another and also the concentration of disinfectant being used.
DISINFECTANTS SHOULD BE MADE UP AS REQUIRED AT THE TIME OF USE

List of Disinfectant Agents Approved For Use

AGENT	TRADE NAME	INDICATION FOR USE
2% Chlorhexidine Gluconate w/v 70% Isopropyl Alcohol individual sachet wipe	Sanicloth PDI wipes Clinell - class iia medical device Other wipes with similar properties	Hard surface preparation for the disinfection of hubs and access ports on vascular access devices, tops of blood culture collection bottles prior to collection of samples or other physically clean equipment where surfaces are compatible with alcohol based preparations.
Chlorine Dioxide	Tristel Duo foam or Tristel Fusion solution	Tristel foam (as dispensed from pump) for high level disinfection of patient equipment by nursing staff Tristel fusion (1 sachet per 5 litres of water) for use by domestic staff for isolation room, terminal cleans and enhanced cleaning e.g. during outbreaks.
Chlorine Dioxide	Tristel three part system • Pre-Clean wipe • Sporicidal wipe • Rinse wipe	A practical and effective way to decontaminate heat sensitive, non lumened instruments when automated methods are not available: • Nasendoscopes • Transoesophageal echo (TOE) probes • Ultrasound probes • Non-lumened medical devices
Ethanol 70% denatured	Spiriclens Trigger	For rapid disinfection of hard surfaces including trolleys, gas cylinders, work surfaces, ward and laboratory furniture and footwear

AGENT	TRADE NAME	INDICATION FOR USE
Hypochlorites or Sodium Dichloroisocyanurates (NaDCC)	Chloros, Milton, Chlorclean Actichlor or Covchlor hospital chlorine tablets Presept granules	Chlorine based solutions should be used for blood spillages in non-carpeted areas. They can be used as part of terminal cleaning of an isolation area, cleaning during outbreaks of infection and for disinfecting surfaces and equipment in some cases. Ensure product specific dilution rates are followed as per manufacturers guidance are used
Hydrogen Peroxide Vapour	ProXcide	Both act as high level disinfectants for use on physically clean equipment and surfaces to achieve total room decontamination. Effective against bacteria, viruses and spores but has to be used in an unoccupied area which is sealed. Refer to RVAG (Red, Violet, Amber, Green) type of clean system poster for specific conditions of use.
Ultra-Violet C	Ultra-V	

Disinfectants for Instruments

Instruments must be physically clean prior to being disinfected.

Heat disinfection is always the preferred method. Where this is inappropriate for heat labile equipment the following guidelines below should be adhered to. Seek advice from the Infection Prevention Team. For flexible endoscopes see the Decontamination of Endoscopes Protocol.

Chemical Disinfectants Guidelines for General Use

There are a number of important factors that must be considered when using chemical disinfectants:

- All chemical disinfectants must be clearly labelled and used within the expiry date. They should be freshly prepared. They must be used at the correct concentration and stored in an appropriate container.
- Chemical disinfectant solutions must not be mixed or detergents added unless they are compatible.
- Disinfectant or detergent solutions must not be prepared and stored in multi-use containers for occasional use. Solutions prepared and stored in this manner may easily become contaminated

with micro-organisms; using such solutions will therefore readily contaminate a surface rather than clean it.

- Manufacturer's instructions must be consulted on compatibility of materials with the method of sterilization or disinfection.

8.0 Tracking and Traceability

8.1 Tracking: refers to a process for identifying the current, past and future locations of a device or item. Tracking provides definitive accurate information about objects of an inventory or any stock of mobile entities.

8.2 Traceability: refers to the completeness of the information about every step in the process chain. It is the ability to verify the history, location, or application of an item by means of examining the documented recorded information within the tracking system above provided the item has a unique identification mark and that mark remains with that device or item or is traceable to that item in the event of a documented change to its unique identity. This unique identifier should never be removed for the life of an item or device – doing so will eliminate the history of such a device and allow for the risk of mixing devices of a similar type and the associated tracking data.

8.3 Systems must be in place to allow medium-risk and high-risk re-usable medical devices such and surgical instruments to be tracked through decontamination processes in order to ensure that the processes have been carried out effectively.

8.4 Systems must be in place to allow tracing of medium-risk and high-risk re-usable medical devices and be linked to the patient that they were used on. This is to facilitate look-back exercises should they be required for public health or infection prevention purposes.

8.5 Track and trace is also fully applicable to loan items and must be done in accordance with Trust procedures and the requirements of the system in place within Sterile Service Departments and within the detail of the SLA in place.

9.0 Transport

Transport of contaminated medical devices is subject to the Transport of Dangerous Goods Act 1992 and as such must be transported in suitable containers and trolleys which conform to the relevant standard.

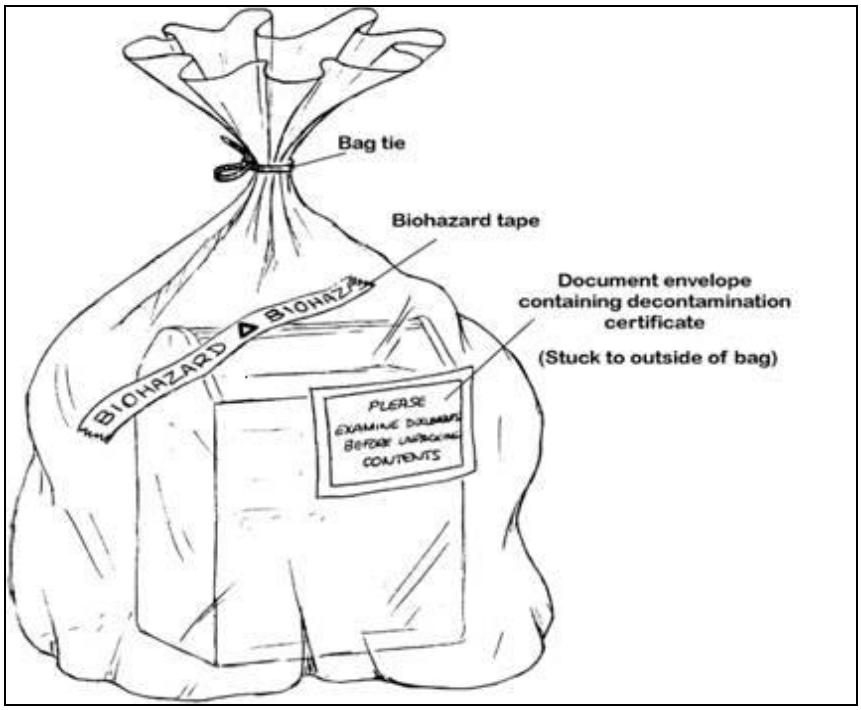
Containers and trolleys must be cleaned after each use. Documented records of the cleaning must be kept. The Trust must ensure that transport and delivery personnel are trained in accordance with the Transport of Dangerous Goods Act 1992.

9.1 All medical devices must be decontaminated prior to transportation between wards and departments including requesting maintenance from the estates, electro biomedical engineering (EBME) departments or third party contractors.

9.2 A decontamination of equipment certificate must be completed and accompany each piece of equipment when sending for servicing, maintenance or repair. Sterile service departments will use the decontamination certificate specified within their quality management system.

9.3 Where items of equipment cannot be fully decontaminated, they should be placed in a clear plastic bag with a biohazard label clearly and firmly attached to the front. A document envelope containing the decontamination certificate attached to the outside of the bag.

9.4 If a device or piece of equipment is placed for collection, service or repair, but does not have a completed Decontamination of Equipment Certificate, OR in the event it is visibly soiled, the action set out on page 17 must be followed.



9.5 If there is a potential of an item being used on another patient prior to it being transported for decontamination it must be clearly labelled as contaminated.

10. Storage of Sterile items

10.1 Storage conditions of sterile or clean items must be designed to minimise deterioration and prevent contamination or damage to products. The facilities must be easy to clean and enable stock rotation at user level.

10.2 The departmental manager is responsible for the area in which medical devices, instrumentation sets and any other items requiring storage.

10.3 The Storage must be in accordance with HTM 01-01, and any other regulatory and non regulatory requirements in place within the Trust.

Storage shall provide: and where necessary in accordance with manufacturer's guidance:

- A dust-free environment – suitable air changes and ventilation rates.
- Protection from artificial lighting and direct sunlight.
- Temperature control and protection from excessive heat which may come from: i.e: radiators or strip lighting.
- Off the floor shelving.
- Protection from moisture – within humidity range specified by a manufacturer.
- Protection from damage or sharp objects.
- Free from infestations

10.4 It is the responsibility of the person obtaining any item for use to check the integrity of wrapping/packaging before using a sterile medical device product or item of equipment. This should be done as far in advance as practicably possible as there may be a requirement for the item to be reprocessed if damage is identified. **All items should be fit for their intended purpose at the point of use, in date and free from damage.**

10.5 If problems are identified with damaged wrapping this must be reported to the manager of the department and documented in accordance with the requirements in place within the Trust. Storage and handling conditions should then be checked. If these are not compliant with the guidance above, then the departmental Manager responsible for that area must investigate the problem. This also applies to any item purchased externally. In the case of products and Items reprocessed and packaged by sterile service departments the local procedure within the quality management system must also be followed. Clarification on the local process for this must be sought from the local Sterile Services Manager to ensure problems with packaging are appropriately reported. All other applicable Trust recording mechanisms must be followed.

11. Purchase and Acquisition of Instruments and Equipment

All procurement requirements must be followed and a Pre Purchase Questionnaire completed (PPQ) prior to any purchases being made. Only the current up to date form is used. All items must be assessed and approved prior to purchase by all relevant departments. This assessment and approval process must include users, medical equipment advisor, Infection Prevention Team and the Sterile Services Manager (For items which will be reprocessed by SSD), Contracts/Procurement and when necessary the Authorised Person (Decontamination). The personnel involved will be in dependant on the type of item being purchased and whether this is a high, medium or low risk item. This will ensure that items are appropriate for the clinical use intended, and comply with all relevant regulatory and non-regulatory and HTM requirements relating to equipment purchase specifications.

Total lifecycle funding from purchase, maintenance service, testing and validation requirements to end disposal must also be fully considered arranged and secured prior to purchase of any item. Where applicable the appropriate department/s must be consulted this will include departments responsible for servicing items (Siemens – WRH, Technical Services – Alex, KTC).

Services which cannot be provided by these departments will need to be arranged with the manufacturer of the item or a competent appropriate service provider. The service provider must hold the relevant certification and competencies relating to the service being provided and copies of current in date certification should be obtained and kept on file. A detailed service level agreement for the service being procured must also be arranged. This must be in accordance with manufacturer's recommendations, HTM or other equipment maintenance, servicing and testing requirements. Service level agreements must not be allowed to elapse. No order for any medical device or item of equipment is to be placed prior to all of the above requirements being arranged.

The above also applies to any medical device or item of equipment being loaned or on trial. All of the relevant indemnity processes and documentation in place within the Trust must be followed.

12. Loaned Items of Equipment

12.1 There may be instances where the purchase of specialist or very low usage instrument sets/items of equipment for use in specialist procedures would be uneconomical for the Trust to purchase and maintain. In this instance loan sets may be used which are supplied by an external source, used for that procedure only and returned.

12.2 Using loaned pieces of equipment increases the risks associated with the decontaminating and reprocessing of medical or equipment as they are not familiar to the Trust. In all instances all loan sets or equipment must be provided with the Manufacturer's Instructions for use, to include decontamination instructions which must compatible with Trust decontamination / sterilisation services and processes. A Declaration of Decontamination status / Certificate of decontamination along with a full inventory and check list / pictures of items supplied should be made available to the processing SSD or other staff well in advance of processing the items. These records must be retained in line with normal requirements for the retention of records in case they are required in the future. They will also be required for any internal and external audit requirements. Unique traceability codes will be allocated to items for the duration of the loan.

12.3 In the case of surgical instrumentation sets, maintaining set integrity is vital to minimise instrument migration and enable traceability to the patient. This includes the control of individual instruments within loaned sets to audit their removal and replacement.

12.4 The loan set procedure in place within the local sterile service department must be adhered to at all times. This will be detailed within the SLA in place. The local Sterile Service Manager will be able to provide advice.

12.6 A record of every loan set should be kept by the department arranging the loan and should include all relevant codes and dates to ensure traceability; records should be kept in line with the policy for the retention of records.

13. Alternative Sterilisation / Decontamination Technologies

Approval of any alternative decontamination technology in the future must be via the Authorised Person (Decontamination), the Infection Prevention Team, and Decontamination Committee.

14. Action In Response To HSG 93/26 Decontamination of Equipment Prior to Inspection, Service or Repair

- Anyone who inspects, services or repairs medical and laboratory equipment either on NHS premises or elsewhere has the right to expect that articles have been properly treated so as to remove or minimise the risks of infection.
- Equipment and articles used for invasive procedures, analysis and diagnosis which come into contact with blood, body fluids / tissue or other pathological specimens will require decontamination prior to examination.
- Equipment which is visibly soiled with blood / body fluids and is accessible to cleaning must never be presented or sent to a third party for maintenance or repair.
- All decontamination procedures should be undertaken by suitably qualified staff. The method of decontamination used must be one that does not damage the article or any of its components.
- A **Declaration Of Decontamination Status Certificate** must be fully completed in the department before any equipment is sent for repair, to confirm it has been cleaned effectively. This is the responsibility of the person in charge of the ward/department. This should be given to the porter / technician when equipment is collected for repair / service, and remain with the equipment until it reaches its final destination. See Appendix A.
- This also applies to equipment being sent outside the Trust for servicing or repair.
- If equipment is not visibly clean and/or does not have a Declaration Of Decontamination Status Certificate completed, it will not be collected for service/repair.
- In this circumstance the clinical area must be informed that it requires cleaning and a Decontamination Status Certificate completing. If the clinical area cannot be identified, the Matron for the area must be bleeped and informed of the issue so that they can take action. A datix report must be completed
- Any item returned to the workshop and found on inspection to be visibly soiled will be returned to the sending clinical area for cleaning, and a Datix report completed by Technical Services/ Siemens.

In certain situations equipment may not be decontaminated prior to inspection, service or repair, either because the equipment is subject to investigation as the result of a complaint or it cannot be adequately decontaminated without engineering assistance: for example if a part has jammed and

cannot be opened. In such cases the advice of the investigating body should be sought. If such an item is to leave the Trust, the following precautions must be taken:-

- A prior warning should be given to the intended recipient.
- The condition of the item should be clearly labelled on outer packaging.
- The packaging must be suitably robust to ensure contamination will not occur during transportation.
- The agreement of the transporter may be required.
- In case of doubt regarding the decontamination of equipment advice should be sought from a member of the Infection Prevention Team.

Maintenance and Testing of Decontamination Equipment

14.1 HTM Guidance requires that a permit-to-work system should be used for all maintenance and testing procedures on decontamination equipment. Within WAHT this takes the form of a permit to work.

14.2 This will ensure the formal removal of equipment from use, and return to service is documented and will provide certification of acceptance by the User.

14.3. In the event of a breakdown, routine maintenance or validation procedure, the first two sections of the permit-to-work form must be completed by the Designated User before handing over the machine to the Competent Person [CP(D)]. The CP(D) must complete section 3 and 4 of the form after completing the work, confirming that the machine is being handed back in good working order. The Authorised Person AP(D) should review and sign-off section 4 of the permit. The Designated User will need to complete part 5 of the permit to declare that they have received back the machine is good working order. See Appendix B for the Permit-to-work.

14.4 For further information on this process please contact the sterile services department Manager for the hospital unit for SOP or alternatively the designated person or user for the related department.

14.5 Equipment with internal fluid ingress will need to be bagged and sent to Technical Services/ Siemens for disassembling and evaluation of the damage caused, prior to cleaning, decontaminating and drying appropriately. Any equipment, or part that is deemed contaminated beyond economical repair shall be condemned and kept in the yellow bin for incineration.

15. Facilities Required For Local Decontamination

MHRA, NHS UK, HBN and HTM guidance states that cleaning and decontamination including sterilisation of medical devices must only be performed in areas that have suitable facilities. Where appropriate the Authorising Engineer (Decontamination) should be consulted.

Advice must be sought from Infection Prevention Team, Authorised Person (AP), Estates and Facilities Management prior to the commencement of any new project or project improvement of local decontamination facilities. The AE (D) employed by the Trust must be consulted. The information below is for consideration and guidance. For anything other than the cleaning of low-risk items this includes:

- A dedicated decontamination room, separate from the clinical room.
- The area must be planned to facilitate workflow and prevent mixing of clean and dirty items and procedures, including prevention of splash/aerosol contamination. Where possible complete physical separation of clean and dirty areas should be achieved.
- All surfaces and finishes within the area must meet the requirements of the applicable HTM and any other HBN or Trust Requirements.
- Suitable areas for the storage of all items required and any PPE.
- Ventilation of areas must meet minimum standards as specified in HTM, HBN and any other regulatory and non regulatory requirements. Health & Safety and Estates advice should be sought.
- A separate hand washing sink is required. The taps and water supply to this must be in accordance with Trust specifications.
- A sink for cleaning and a separate rinsing sink are required: both must have the appropriate taps and water supply must be in accordance with the Trust specifications. A suitable plug and an overflow outlet.
- Automated washer-disinfector facilities where possible and applicable. Also the consideration of the use of pass through models to achieve optimum clean/dirty separation and workflow.
- Appropriate detergent in accordance with local procedure, cleaning cloths and appropriate cleaning brushes which should be single-use items.
- Adequate personal protective equipment, including mouth and eye protection.
- Spillage kit and protective equipment for use in the event of emergency spillage.
- Eye Wash Station.

16. Monitoring of Compliance and Escalation

16.1 Escalation relating to any issue will be done in accordance with normal reporting and governance arrangements.

16.2 Monitoring of local policies and standard operating procedures will be set out in the documents produced by the relevant services and departments based upon the principles set out here. Requirements and arrangements will necessarily vary considerably depending on services involved.

16.3 Overall monitoring of compliance with these principles will take place via the Decontamination Committee, and also through the Health & Safety Committee via review of Datix reports and other issues escalated through that route.

17. References

Control of Substances Hazardous to Health Regulations (COSHH) (2002) Health & Safety Executive.

Health & Safety at Work Act (1974).

Health Technical Memorandum HTM01-01 Decontamination of medical devices within acute services..

Medicines and Healthcare Regulatory Agency (MHRA) – Managing Medical Devices (2021)

Local policies and Standard operating procedures; including for the following departments and services:

- Sterile Services Department
- Cardiology
- Radiology Ultrasound
- Women & Children's Division Ultrasound
- Endoscopy Services
- Theatres
- Tissue Viability Mattress Decontamination Facilities
- Bed and mattress deep clean facilities
- Technical Services Dept
- Siemens

Members of the Working Group:

Name	Title
Tracey Cooper	Director of Infection Prevention & Control

Steve Steward	Sterile Services Manager

Consultation

This key document has been circulated to key stakeholders and representative of the target audience for comment prior to finalisation before being submitted for approval by IPCSG

Name	Designation
All members of Decontamination Committee, including AE(D)	

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Name	Committee
Paula Gardner	Infection Prevention & Control Steering Group

Appendix A:

DECLARATION OF DECONTAMINATION STATUS CERTIFICATE

Prior to the inspection, servicing or return of medical and laboratory equipment.

TO / RECIPIENT:	**MAKE:**	**DESCRIPTION:**

MODEL:	**Technical Services / Siemens Asset Number:**
SERIAL and or BATCH NUMBER:	

1. *(Circle **A** if applicable, otherwise complete all parts of **B** providing further information as requested or appropriate)*

A

This equipment/item has not been used in any invasive procedure or been in contact with blood, other body fluids, respired gasses or pathological samples. It has been cleaned in preparation, for inspection, servicing, repair or transportation.

B

Has this equipment been exposed internally or externally to hazardous materials as indicated below?

YES **NO** Blood, body fluids, respired gasses, pathological samples
YES **NO** Other biohazards
YES **NO** Chemicals or other substances hazardous to health
YES **NO** Other hazards: state what:- _____

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2. Has this equipment/item been fully cleaned and decontaminated in accordance with trust policy and manufacturers guidelines?

YES **NO** If this equipment/item has been cleaned and decontaminated please indicate methods used:

Automated washer disinfector ☐ Steam sterilisation @ 134°C – 137°C ☐

Manual external clean: Clinell wipes ☐ Surface disinfection: Tristel Fuse ☐

If another product was used for manual cleaning or surface disinfection, please state what was used:

If this equipment could not be cleaned, please indicate reason:

Such equipment must not be returned / presented without the prior agreement of the recipient whose contact name must be given above.

3. Has the equipment been safely prepared to ensure safe handling and transportation? **YES** **NO**

I declare that I have undertaken all reasonable steps to ensure the accuracy of the above information in accordance with HSG (93) 26.

Authorised Signature:	**Print Name:**

Position:	**Department:**	**Date:**

IF THIS FORM IS NOT FULLY COMPLETED – THE ITEM WILL NOT BE TAKEN FOR SERVICE OR REPAIR

Appendix B

Worcestershire Acute Hospitals NHS Trust

Technical Services
Alexandra Hospital

Permit No. : 000100

DECONTAMINATION - PERMIT TO WORK SCHEME

Part 1 - User

Job Ref. Number		Asset/Machine No.		Date Permit Issued	/ D	/ M	/ Y

Tech. Services Job Ref. No. is required only for Part 2b: 3,4,5 and 6

The equipment specified in Part 2a below may be taken our of service for an estimated ____ hours/days

Commencing / D / M / Y

I declare that the equipment has been decontaminated and notices affixed to indicate 'Work in Progress'

Signed User _____ Print Name _____

Part 2a - User

Type of equipment

Tick the appropriate box below

1 Thermal washer-disinfector
2 Chemical washer-disinfector
3 Porous load sterilizer
4 Other (please specify)

Part 2b - User

Work to be performed

Tick the appropriate box below

1 Routine maintenance
2 Weekly periodic testing
3 Breakdown maintenance *
4 Quarterly periodic testing
5 Yearly periodic testing
6 Installation/PQ/PRQ

* Details of the Routine maintenance:

Part 3 - CP(D)

I accept responsibility for carrying out the work specified in Part 2b on the equipment identified on Part 2a

No attempt will be made by me or by any person under my control on any other part of the installation

I am fully conversant with the relevant health and safety precautions relating to the work required

Signed CP(D) _____ Print Name _____

Signed CP(D) takng over _____ Print Name _____

Part 4 - CP(D)/AP(D)/AE(D)/Microbiologist (Sterilizers)

☐ If Part 2b, only 1 and 2 or both are being performed, this declaration need only be signed by the CP(D).

☐ If Part 2b, 3, 4 or 5 are being performed, this declaration requires the signature of the CP(D) and AP(D).

☐ If Part 2b, 6 is being performed, this declaration requires the signature of the AE(D).

If Part 2b, biological indicators are involved, this declaration will also require the signature of the Microbiologist (Sterilizers).

I declare that the work specified in Part 2b on the equipment identified in Part 2a has been successfully completed

		Date		
Signed CP(D)			Print Name	
Signed AP(D)			Print Name	
Signed AE(D)			Print Name	
Signed Microbiologist			Print Name	

Part 5 - User

I have ensured that all the required signatures have been entered in Part 4.

I have removed the 'Work in Progress' notices and accept the equipment specified in Part 2a back into use.

Signed User		Print Name	
Date of acceptance	/ D / M / Y	Time of acceptance	hours/days

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