Decontamination of Reusable Medical and Surgical Devices

N.B. Staff should be discouraged from printing this document. This is to avoid the risk of out of date printed versions of the document. The Intranet should be referred to for the current version of the document.

(Please contact Health Board Decontamination Officers and NHS Wales Shared Services Partnership/Facilities for further information on updated guidance within NHS Wales)
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1 Executive Summary

The Policy has been developed to provide clear information to staff at all levels of the organisation on what is required for the safe and effective decontamination of reusable medical and surgical devices. This Policy covers the life cycle of such reusable devices, from procurement to eventual disposal and the requirements for safe decontamination including storage and transportation.

Effective decontamination that renders medical devices safe for use is a fundamental component of any healthcare service. Decontamination that is not carried out appropriately can result in the risk of transmitting infection to patients and also to staff handling the equipment.

The policy is divided into sections covering each element of the life cycle of a reusable medical device and incorporates current regulatory requirements and best practise guidance for healthcare organisations within NHS Wales. It will also contribute toward meeting the requirements of latest guidance including Welsh Health Technical Memorandums.

1.1 Scope of policy

The Policy applies to staff who are responsible for and/or involved with any element of the decontamination process for reusable medical devices and focuses on medical devices or equipment categorised as high or intermediate risk.

- High risk medical devices are those that penetrate skin or mucous membrane, vascular system or sterile cavities e.g. surgical instruments, laparoscopes etc.

- Intermediate risk medical devices are those that come into contact with intact mucous membranes or maybe contaminated with particularly virulent or readily transmitted organisms e.g. sigmoidoscope, bronchoscope etc.

- Low risk medical devices are those that come into contact with intact skin or do not come into contact with the patient e.g. blood pressure cuff etc.

The term reusable medical device applies to all such devices whether owned by the Health Board, rented, or on loan.
Exclusions:

Items that are marked with the single use symbol are not covered by this policy.

Items that are designated as “single patient use” are not covered by this policy; the instructions supplied by the manufacturer must be followed for these items recognising they must be compliant with current decontamination standards.

This policy does not provide specific advice on the decontamination of flexible endoscopes and their accessories. A specific policy is available for staff involved in the decontamination of this specialised equipment.

This policy does not provide specific advice on the decontamination of dental equipment, and their accessories. A specific policy is available for staff involved in the decontamination of this specialised equipment.

This policy does not provide specific advice on the use of bench top sterilisers. A specific policy is available for staff.

2 Aims

Effective decontamination of medical devices will be carried out to ensure that the device is:

- Safe for further use
- Safe for members of staff to handle
- Safe for use on the patient
- Safe for disposal

2.1 Objectives

The policy will achieve its aim by:-

- Clearly identifying roles & responsibilities in relation to the management of the decontamination process.
- Making explicit the importance of each stage in the decontamination process.
- Setting out the requirements that will ensure effective decontamination is achieved to prevent transmission of infection.
- Ensuring staff who handle and decontaminate reusable medical devices are protected from exposure to potentially pathogenic
micro-organisms and chemicals used in the decontamination process.

3 Policy Statement

To ensure that there is a system in place that ensures as far as is reasonably practicable all reusable medical devices are appropriately decontaminated prior to use and that the risks associated with decontamination facilities and processes are adequately managed. (Appropriately = in alignment with manufacturer’s instructions and national guidance)

4 Responsibilities

It is important that all staff, patients and carers understand their roles and responsibilities in relation to the decontamination of reusable medical devices.

4.1 Decontamination Lead

The Decontamination Lead will provide the strategic lead for decontamination and will be responsible in ensuring that this policy is implemented in relation to the organisation and takes proper account of relevant national guidelines.

4.2 Decontamination Manager

The Decontamination Manager with support from the lead Infection Control Doctor/Consultant Microbiologist and the Infection Prevention Team is responsible for the production, review and audit of the evidence-based policy to provide the Health Board with up-to-date information on the decontamination of reusable medical devices and will provide staff with training on this policy where needed.

4.3 Strategic Decontamination Group

The role of the Strategic Decontamination Group is to provide strategic direction and develop a structured approach to the decontamination of reusable medical devices that eliminates or reduces as far as possible the risks associated with the decontamination process to the patient, user and third parties. The Group is accountable to the Health Board and reports to the Infection Prevention & Control Committee. Task and Finish groups as appropriate will feed into the Strategic Decontamination Group.
4.4 Ward and Departmental Managers

Ward/Department Managers must ensure that staff are aware of this policy and have the necessary resources for implementation.

4.5 Staff

All staff are responsible for ensuring effective decontamination takes place and they are competent to carry out the appropriate process. Staff involved in any aspect of the decontamination process of reusable medical devices are responsible for adhering to this policy.

In addition, key persons and responsibilities as defined in detail in Welsh Health Technical Memorandum (WHTM) 0101Part A (2013) are in place as follows.

- **The Executive Lead** is identified as the person with ultimate management responsibility for the operation of the premises and the decontamination process.

- **The User** is the person designated by management to be responsible for particular elements of the decontamination process. In a hospital the user could be the HSDU (Hospital Sterilisation and Disinfection Unit) manager, theatre manager, endoscopy clinic manager, ward manager or laboratory manager. Dentist or other health professional.

- **The Authorised Person (Decontamination)** is responsible for the practical implementation & operation of Management’s safety policy & procedures relating to engineering aspects of decontamination equipment.

- **The Authorising Engineer (decontamination)** provides independent auditing, and advice on decontamination, together with reviews and witness/validation of processes. This role is fully independent of the Health Board.

- **The Competent Person (Decontamination)** is designated to carry out validation and periodic testing on sterilisers and washer disinfectors (as per WHTMs).

- **The Microbiologist** is designated to be responsible for advising the user on microbiological aspects of decontamination with support from the Decontamination Manager.
• **The Lead Infection Control Doctor** is defined as the person designated by management to be responsible for advising the user on all aspects of infection control.

Co-ordination of decontamination Health Board wide is the responsibility of the Decontamination Manager who reports to the Strategic Decontamination Group and the Infection Prevention & Control Committee.

5 **Introduction**

Decontamination of reusable medical devices is a combination of processes, which if not correctly undertaken, individually or collectively, may increase the likelihood of micro-organisms being transferred to patients or staff. This combination of processes includes acquisition, cleaning, disinfection, inspection, packaging, sterilisation, transportation and storage (see figure 1 below).

6 **Requirements for Effective Decontamination**

An effective management control system is in place covering all aspects of the decontamination life cycle.
• Appropriate equipment is procured and provided, which is:
  • Fit for purpose
  • Properly maintained with appropriate records
  • Properly monitored and validated with appropriate records
  • In compliance with WHTMs & other expert guidance

• Appropriate facilities are provided for the decontamination process

• Staff are properly trained, supervised and assessed as competent

• Single use items are not re-used

• Appropriate records of the decontamination process are kept

• Decontamination is undertaken in a dedicated Sterile Service Department accredited to the Medical Device Directive department wherever possible (Welsh Government policy)(WHTM 0101 part A)

• ‘Instruments should be transported to the sterile services department (SSD) immediately after the close of a procedure, for cleaning and reprocessing as soon as practically possible.......If devices cannot be returned in a timely manner, it is important that the instruments are kept moist using appropriate methods approved and verified by the SSD’ Prevention of CJD and vCJD by Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Subgroup (2015)

• Where possible, decontamination should be automated

• Systems are in place to trace instruments through the decontamination cycle and link them back to patients on whom they have been used

• Decontamination should be undertaken in a manner that does not present a health & safety risk

• Policies and procedures exist for all aspects of decontamination work

7 Health & Safety
All decontamination processes must be carried out with regard to the health and safety of patients, staff, and visitors. This includes assessing practices against guidance and regulations, and monitoring these to ensure that appropriate procedures are being followed. In addition, it involves assessing equipment, and ensuring that appropriate scheduled maintenance procedures are undertaken to check that equipment is properly installed and maintained, and that it is functioning in a safe manner as designed and commissioned.

Appropriate personal protective equipment must be available within the department and staff should have received training on the appropriate use of the equipment as part of their induction with updates as agreed within the department.

Chemicals used in the decontamination process must be compatible with process, risk assessed and used in accordance with COSHH regulations. COSHH data sheets must be available. Staff working with or previously have worked with such chemicals should attend annual health checks with the Occupational Health Department. Should a member of staff develop any adverse reaction they must immediately report this to their line manager or supervisor and contact Occupational Health for advice and review.

8 Acquisition of Reusable Medical Devices

8.1 Procurement

Purchasing decisions have implications on the decontamination process. There will be two types of purchase; a reusable medical device that requires decontamination before re-use and the purchase of an item of equipment whose function is to decontaminate a reusable medical device(s).

During the procurement process for new reusable medical devices, consideration should be given to how they will be decontaminated and whether facilities are available to undertake the decontamination process. The cost of the decontamination process should also be assessed and in some instances it may be cost-effective to opt for single use. When considering the option of single use equipment, the costs associated with its disposal e.g. increased clinical waste disposal costs should also be considered.

Likewise, it should be ascertained before purchase that any new decontamination equipment is suitable for the medical devices/instruments to be processed and that they meet the
requirements of harmonised European standards, current national guidance and legislation e.g. BS EN 15883/WHTM 0101 part D (2013). It is essential that the decontamination instructions provided by the manufacturer are compatible with the decontamination processes available within the Health Board and comply with the decontamination policy. For example, a manufacturer may state that a medical device can be steam sterilised at 121°C, but this would not be compatible with our sterilisation process in HSDU which operates at a higher temperature.

Where manufacturers’ instructions do not meet the WHTMs requirements, then a thorough risk assessment should be made with key individuals such as decontamination manager, relevant clinician, lead infection control doctor, HSDU quality manager and medical devices manager. In the initial absence of manufacturer’s not being able to adjust instructions to meet the required standards, the risks should consider both impact to the patient and organisation if such equipment is omitted or introduced.

Before purchasing washer/disinfectors that require chemicals to achieve disinfection, the type of disinfectant and its compatibility with both the reusable medical device and the washer disinfector must be duly considered.

Washer disinfectors that achieve disinfection through reaching high temperatures to fulfil thermal disinfection conditions can be used for equipment that is not heat sensitive, the manufacturer’s instructions should be checked for compatibility.

As part of the developing Health Board Decontamination Strategy, standardisation of decontamination equipment is preferred and all purchases must be made via the Procurement Board through the appropriate procurement process. Procurement of such equipment should only be completed once a formal technical specification is completed and submitted as part of procurement contract. Ensure NWSSP / FS and AE(Decontamination) are involved in the specification (WHTM 0101 Part B).

Purchases should be the most economically advantageous solution, rather than the cheapest initial outlay. Staff training and maintenance issues must also be considered and it is essential that the Infection Control Team, Authorising Engineer (Decontamination), Estates Management and Decontamination Manager are included in the decision making process. The Authorised Person (Decontamination) is a source of expert
knowledge on engineering aspects of decontamination processes and can be contacted to provide advice on individual purchases. Involvement of key staff in the purchasing decision will ensure that the equipment is compatible with Health Board policy and current guidance.

8.2 Loan

Reusable medical devices acquired on loan are subject to the same decontamination requirements as set out in this policy. All surgical instruments and associated equipment entering the organisation, regardless of the source, should be cleaned and sterilised before and after use in accordance with the manufacturer’s instructions. Only reusable medical devices that are compatible with the Health Board’s decontamination methods and policy should be acquired on loan. Records must be kept for traceability purposes and in line with the requirements of the Health Board’s policy on The Management of Medical Equipment and Devices Policy (2013).

Departments should produce their own policy/procedure in relation to loan of specialist equipment that covers initial inspection, decontamination, documentation, and traceability records. Indemnity forms must be completed for any item borrowed or as a free issue from the manufacturer or loaned between organisations and principles of standardisation should be adhered to (please refer to the Management of Medical Equipment and Devices Policy).

9 Decontamination Process

The manufacturer’s instructions for the decontamination of each reusable medical device must be followed. These instructions must be available at local level within the department(s) where the decontamination is undertaken to allow staff easy reference to each step in the recommended process. That is assuming the manufacturer’s instructions are correct and in line with current standard requirements.

Some items may require some dismantling to achieve effective cleaning. The manufacturer’s instructions on reassembly must also be followed carefully. The device should be assembled at the point in the decontamination process advised by the manufacturer. For example in some instances the medical device may need to be dismantled to undergo the sterilisation process and will require assembly by the scrub nurse in theatre, or once washed and disinfected the instructions may state that the medical device must be reassembled for steam sterilisation. It is essential to follow the
manufacturer’s specific instructions for each make and model of the medical device to be decontaminated.

Documented instructions are essential to ensure that the decontamination requirements are performed correctly. All devices will require cleaning prior to either disinfection or sterilisation depending on the type of instrument. The appropriate procedure for each instrument must be followed. Deviation from the recommended decontamination process may result in ineffective decontamination and/or damage to the medical device.

9.1 Selection of the Decontamination Method

Cleaning must always take place before any of the other decontamination processes, as the presence of physical soiling prevents effective disinfection or sterilisation. The level of decontamination required for an item is dependant upon the anticipated use of that item.

9.1.1 High risk items

High-risk items include all reusable medical devices that are in close contact with a break in the patient’s skin or mucous membranes, and devices that enter a sterile body area of the patient. For reusable high-risk items, the appropriate means of decontamination is cleaning followed by sterilisation. All high-risk items must be sterile at the point of use. Examples of high-risk items include surgical instruments, laparoscopes, syringes, needles and catheters.

Decontamination level required: Cleaning and sterilisation.

9.1.2 Medium risk items

Medium-risk items are medical devices used in contact with mucous membranes, items contaminated with particularly virulent or readily transmissible organisms, and items that you intend to use on an immunocompromised patient. In certain circumstances it may be preferable to transfer the items to the “High Risk” category. Disinfection by heat (known as thermal disinfection) is preferred where this is possible. For reusable medium-risk items, the appropriate means of decontamination is cleaning followed by disinfection (or sterilisation). Examples of medium-risk items include respiratory and anaesthetic equipment, gastrointestinal endoscopes and thermometers.

Decontamination level required: Cleaning and disinfection.
9.1.3 Low risk items

Low-risk items are medical devices used in contact with a patient’s healthy intact skin, and equipment that does not have close contact with the patient. For these items, cleaning is sufficient. However, disinfection may be necessary if there is a known infection risk. Examples of low-risk items include tourniquets, washing bowls, bedding, baths, furniture, toilet seats, floors, walls and sinks.

Decontamination level required: Cleaning and drying is usually adequate, but disinfect if known infection risk.

9.1.4 Minimal Risk Items

Minimal risk items are those items that are not in contact with the patient or his or her immediate surroundings. These items are either unlikely to be contaminated with significant numbers of potentially pathogenic micro-organisms or the likelihood of such micro-organisms transferring to patients and causing infection is unlikely. Examples of minimal risk items include walls, floors, ceilings and drains.

Decontamination level required: Cleaning and drying is usually adequate, but disinfect if known infection risk.

9.2 Cleaning

Instruments should be cleaned as soon as possible after use in an appropriate facility. This may rarely be undertaken within the clinical setting although it should be carried out in the HSDU.

Keeping instruments moist is a requirement, where there is any significant delay prior to cleaning.

Cleaning must be carried out with the most appropriate technique in accordance with the manufacturer’s instructions. Some medical devices may require dismantling to achieve effective decontamination and if necessary training from the manufacturer should be arranged.

Cleaning is the most important element of the decontamination cycle. Poor cleaning will result in the presence of contaminated material remaining on the instruments and affect the quality of the disinfection and sterilisation process.
Wherever cleaning is carried out, staff should be appropriately trained, and wear appropriate personal protective clothing.

Cleaning can be separated into mechanical processes using an automated washer-disinfector or manual processes. An automated cleaning system is preferred as this provides a validated repeatable process. Ultrasonic baths can be used as a pre-cleaning process.

Where automated cleaning processes are undertaken, the IT Process Mapping system used should be ‘backed up’ on the appropriate X Drive. This should be audited regularly e.g. monthly to gain assurance of tracking and traceability.

**9.2.1 Manual cleaning**

Manual cleaning of devices should be restricted to those items deemed incompatible with automated processes. Where manual cleaning is undertaken staff must receive training and be assessed to ensure they are competent. A written procedure that conforms to the manufacturers’ instructions and national requirements must be available. Details of manual cleaning should be recorded as part of the decontamination process for that particular reusable medical device. Non-abrasive implements should be used to prevent damage. Devices with lumens/cannulated or small holes should be cleaned with designated single use cleaning brushes of appropriate diameter where manual cleaning is unavoidable.

Particular attention should be paid to the following:

- Where manual cleaning is carried out, it should be undertaken in an appropriate area, which is separate to the sink provided for hand washing and segregated from the patient area.
- Staff are to be trained in manual washing techniques.
- Staff are to be immunised against Hepatitis B and fit to work in such an environment.
- Appropriate personal protective equipment is to be issued.
- There are to be procedures for monitoring the adequacy of cleaning and rinsing.
- Manual washing procedures are to be recorded.
- Detergents are to be used in accordance with Material Safety Data Sheets and COSHH assessments.

(See appendix 1 Manual Cleaning Procedure)
9.2.2 Automated cleaning

Automated processes provide a validated and repeatable cleaning process. Large washer-disinfectors used for decontamination in facilities such as HSDUs should be purchased using a formal technical specification as accepted by NHS Wales Shared Services Partnership. All washer disinfectors must be capable of being validated in accordance with WHTM 0101 Part D.

Washer-disinfector log books and records should be kept by the designated “user” as defined in WHTM 0101 as opposed to centralised storage.

9.2.3 Ultrasonic cleaning - precleaning process

Where ultrasonic precleaning is used, the equipment manufacturer’s operating instructions must be followed and staff given adequate training in the use of the machine. Ultrasonic cleaning should be used only if recommended by the instrument/device manufacturer.

Ultrasonic action is generated by transducers that agitate the water by creating bubbles. The bubbles implode and dislodge dirt from the surface and joints of surgical instruments.

Ultrasonic cleaners help to clean devices with joints or multiple components that are difficult to clean manually. Ultrasonic cleaners are not recommended for cleaning certain items in particular rubber products which will absorb the ultrasonic waves and reduce the efficacy of the cleaning process.

It is essential that ultrasonic cleaners are used appropriately as indicated in WHTM 0105.

9.3 Disinfection

Disinfection by heat or chemicals will destroy many microorganisms but not necessarily bacterial spores. Chemical disinfection does not necessarily kill all micro-organisms present but reduces them to a level not harmful to health when the item is handled or reused. Disinfection by heat (thermal disinfection) is preferred and chemicals should only be used if heat treatment is impractical or will cause damage to the equipment. Some disinfectants, if used under strictly controlled conditions, may be considered sterilants, although this process may be more accurately described as high-level disinfection. Chemical disinfectants may
not work properly when they are: used on dirty objects; not freshly made up; made up to the wrong concentration, not stored correctly or mixed with incompatible chemicals.

9.4 Inspection

Inspection is an essential part of the decontamination process. Adequate lighting must be available to aid visual checking of the medical devices for cleanliness following the washing process. Any signs of inadequate cleaning must be reported and the medical device rejected, documented and repeat cleaning carried out.

Quality assurance methods should be adopted to assist in this process; eg, magnification use and ATP.

Medical devices should also be checked to ensure they are functioning correctly, in good condition and fit for further use.

9.5 Packaging

Reusable medical devices that are processed in the HSDU steam sterilisers (autoclaves) can be packaged before sterilisation. The sterilisers within the HSDU are known as porous load sterilisers because moist heat will penetrate and sterilise the packaged instruments. The wrapped medical devices remain sterile when they are removed from the autoclave until the pack is opened or damaged. Packaging materials must conform to the relevant BS EN standards and be compatible with steam sterilization process.

Before opening a HSDU processed pack it is important to check that:

- It is within the expiry date
- There is a label indicating the date of sterilisation
- The indicator tapes (or arrows on see through packs) have changed colour indicating that the pack has been through a sterilisation process.
- There is no damage to the integrity of the pack or evidence of water contamination such as condensation or dampness.

Sets of theatre instruments are packed in trays with a flexible wrapping material, in reusable containers or in orientation trays. These will be decontaminated after use by HSDU when returned. Flexible packaging materials should be purchased that comply with
the relevant British/European Standards. Heat sealing equipment should be maintained, validated and monitored.

9.6 Sterilisation

Sterilisation is a process used to render an object free from all micro-organisms including all viruses and bacterial spores.

Where sterilisation is necessary, the method of choice in a healthcare setting is steam sterilisation. Sterilisation processes have to be validated prior to use, regularly maintained and their performance routinely monitored.

For reusable medical devices that are heat sensitive and unable to tolerate high temperatures an expensive alternative may be sterilisation with Ethylene Oxide. However, this can be time consuming as the item will need to be sent external to the organisation.

**Definition of validation**

= A documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

9.7 Traceability of Reusable Medical Devices

Systems must be in place to ensure that reusable medical devices including surgical instruments and endoscopes are tracked through the decontamination process. Tracking of instruments through the decontamination process will demonstrate that all elements of the decontamination process have been carried out effectively. Records must be maintained.

9.7.1 Traceability of Surgical Instruments

Surgical instruments are tracked by instrument sets and individual supplementary instruments cannot be tracked in the same way. Ideally all individual reusable instruments should be traceable but current systems do not allow this to be feasible. However, where a device has a unique identifier this should be used as a means of tracking. The feasibility of tracking all instruments should develop with improvements in technology and production of instruments with unique coding and the Health Board policy will be amended to reflect this as new systems are developed.
Records should be maintained for all instrument sets processed identifying:

- the cleaning and sterilisation process used
- the name of the person undertaking the decontamination and;
- details of the actual item being processed.

This information is required so that instrument sets can be traced if required in the event of a failure in the decontamination cycle or for infection control reasons. Records should be kept for a minimum of 21 years. Permanent records should be kept for medical devices that require quarantine or destruction due to contamination with CJD or its variants. Paper documents are acceptable but where space is limited, consideration should be made to archive such information electronically. Whichever system is used, such data must be accessible and evidenced through auditing means.

10 Transportation of Processed Medical Devices

Medical devices that have been through the decontamination process must be segregated from contaminated instruments during transportation. Staff responsible for transporting such medical devices and equipment must be trained in the appropriate handling, collection and delivery process.

11 Storage

All devices following decontamination should be stored correctly in a designated area that is controlled and secure and inaccessible to the public.

11.1 Sterile Packs

A dedicated storage area should be available which is appropriately designed to:

- Provide a controlled environment suitable for storage
- Prevent damage to packs
- Allow strict rotation of stocks
- Allow ease of cleaning
- Allow free movement of air around the stored pack.
- Keep product off floor level
- Keep product dry and secure away from direct sunlight
- Prevent infiltration by insects etc

Inadequate control of these areas may have an adverse effect on the integrity of the sterile product and subsequently render it unsterile and unsuitable for use.

11.2 Locally processed items

Medical devices that are processed locally should be stored in accordance with the manufacturer’s instructions.

12 Use

The medical device should be inspected before use to ensure it is as expected. Should there be any visible soiling the device must not be used. In the case of items from the HSDU, a Health Board Datix entry should be completed and the HSDU manager or supervisor informed. If the device was processed at department level, any discrepancy with the decontamination process must be investigated. The whole process should be checked for failures and a Datix entry completed. Once the cause is identified, steps must be taken to prevent or minimise the risk of recurrence.

Following use, contaminated medical devices must be segregated to avoid:

- spills
- generation of aerosols
- inappropriate use
- contact with environmental services
- contact with staff, patients or visitors

If decontamination is being undertaken locally, the contaminated medical devices should immediately be placed in the designated area within the decontamination room for processing.

Medical devices that are being sent to the HSDU should be returned as per agreed process with HSDU; ie placed into closed containers. They should be transported as soon as possible after use to the HSDU considering the use of ‘moist retaining’ products if any delay is likely.

13 Transportation of contaminated medical devices
Contaminated medical instruments are regarded as UN3291 Clinical Waste, on the basis that they are being transported as healthcare waste for the purpose of recycling.

Used medical devices/equipment must be safely confined and contained in UN approved packaging/containers that are rigid, and leak-proof to avoid spills, the generation of aerosols and contact with staff or environmental surfaces. Any items that may be sharp must be in packaging that is puncture resistant.

Any re-usable packaging must be thoroughly disinfected and sterilised before re-use.

Contaminated equipment must be kept separate from clean decontaminated equipment during transportation by physical barriers, through the use of separate containers and segregation of clean and dirty within the transport vehicle.

Records must be kept of vehicles and containers used.

Training must be provided to staff who handle, collect and transport contaminated medical devices/equipment to ensure that they are aware of the correct procedures to follow. Personal protective equipment must be available for staff at all times and training on its correct use should form part of their training.

Clinical waste should be clearly segregated and sharps placed in properly constructed containers (BS 7320).

If a medical device is faulty and requires repair it must be clearly labelled to indicate its decontamination status.

14 Disposal

The Procurement Manager has responsibility for the disposal of surplus and / or obsolete equipment. There is a process that includes disposal options and the Procurement Manager can advise on this.

Disposal of reusable medical devices and any equipment used in the decontamination process must be disposed in accordance with current waste policy and manufacturer’s instructions. Advice can be obtained from the ABHB Waste & Environmental Manager.

When equipment is condemned it should be removed from the equipment inventory and the appropriate condemning forms should
be completed (refer to The Management of Medical Equipment and Devices Policy, 2013).

### 14.1 Scrap

Equipment may require decontamination prior to disposal as scrap and advice should be obtained as above. Equipment that cannot be effectively decontaminated will need to be disposed of safely in accordance with the organisational waste policy (Ref WHTM 0101 part B).

### 14.2 Return to Lender

If items of equipment are to be returned to lender they should have a Declaration of Contamination Status Form attached. Forms are available via the Intranet in the infection control manual. Labels are available from Procurement, EBME and the IT department.

### 15 Facilities Required for Decontamination

All areas where decontamination is carried out should meet appropriate standards for safe and effective management of medical devices through this process.

The ABHB Decontamination Manager, Authorised Person (Decontamination) and on occasion Authorised Engineer (Decontamination), are to be included in any decontamination facility concerns, alterations or new build.

#### 15.1 Equipment

Equipment provided for the decontamination of reusable medical devices should meet recognised specifications as defined in European and British standards. Processing equipment should be suitable for the instruments it is required to process. The physical control parameters that make up the process need to be configured as part of a validation process and there should be no adjustments unless consultation with the AE(D) or AP(D). The process should be routinely monitored in alignment with guidance documents.

#### 15.2 Equipment maintenance

Planned maintenance is an essential part of the decontamination process. Equipment (washer-disinfectors, sterilisers etc.) must be used in accordance with validated processes. These processes should ensure planned preventative maintenance, periodic
calibration and testing to ensure that equipment remains in the validated condition. These processes should also be independent of any monitoring used to control the decontamination equipment. Processes that require validation should only be carried out using automated equipment to ensure reproducibility.

Failure to maintain the equipment and its systems gives rise to the potential for inadequate decontamination.

15.3 Equipment validation and monitoring

Equipment should be regularly tested, monitored and calibrated to the definitions set out in European Standards and departmental best practice guidance, using recognised WHTMs. Processes should be validated and independently monitored, i.e. the equipment which monitors the process should be independent of the control of the process.

15.4 Appropriate facilities provided for decontamination

There should be enough space to allow staff to work in comfort and safety, with good segregation of clean and dirty activities. Lighting should be adequate to allow proper inspections of instruments. Current guidance specifies requirements for decontamination facilities.

Any area in which the decontamination process takes place meets the conditions defined in the source documents and in compliance with the Health and safety at Work Act (1974), including:

- A dedicated decontamination room.
- Accessible from a service corridor.
- Ventilation of areas must meet minimum standards as specified in national guidelines and be appropriate for process chemicals used within environment.
- Having controlled temperatures and humidity.
- Having walls and other surfaces finished with flush junctions, be smooth, non-linting, water resistant and able to withstand frequent cleaning as per infection control advice.
- Having floors sealed with a washable non-slip finish.
- Having adequate lighting available to permit good working practices.
- Hand washing and gowning facilities being located in or near to the decontamination area.
The area must be planned to facilitate workflow and prevent mixing of clean and dirty items and procedures, including the prevention of splash contamination.

16 Training

Staff involved in the decontamination process should receive formal, ongoing training to current recommendations. Staff in clinical units carrying out local decontamination must be trained in the appropriate use of the equipment available within their department. All staff should be properly supervised, their performance monitored and competencies maintained. Where staff require specific training on specialised equipment for example, washer-disinfector or endoscope, training must be provided by the Company. Attendance records should be kept of all staff who receive training and any updates.

Training should include:

- Departmental policies, standards and procedures.
- Infection Control
- Quality issues within the department.
- Health & Safety at Work Act and Health & Safety awareness within their department.
- COSHH Regulations.
- Incident/accident reporting
- Manual Handling
- Safe operation of equipment
- Personal Hygiene, Uniform policy, and dress codes.
- Fire hazards and regulations
- Awareness of relevant HTMs and their implementation.

In addition, the following specific training will also be required for certain staff involved in the decontamination process:

- The correct and safe method of washing instruments manually
- The use of automated reprocessors / washer disinfectors
- The correct documentation of the decontamination process
- Graphical HSDU symbols

Training on this policy will be undertaken by individual decontamination department leads with the support of the Decontamination Manager.

17 Implementation and Monitoring
17.1 **Chief Executive, General Managers and Chiefs of Staff**

To appoint the appropriate personnel identified in section 4 Responsibilities.

17.2 **Quality & Patient Safety Committee**

Include quality and performance measures for the decontamination process as one of the impacts on the quality of clinical service provision.

17.3 **Decontamination Manager**

Compliance with this policy will be monitored through a programme of audit. An annual audit of the decontamination process at department level will be undertaken using an All Wales recognised auditing tool.

18 **Further Information**

Further information is available from the Infection Control Manual particularly the Creutzfeldt-Jacob Disease Policy; and Blood-borne Viruses Policy. See also The Management of Medical Equipment and Devices Policy. There are many sources of information on legislation and decontamination guidance.

19 **References**

- European Agreement Concerning the International Carriage of Dangerous Goods by Road 2012 (ADR 2012 Accord Dangerous Routiers)
- Health and Safety at Work etc Act (1974)
- The Management of Health & Safety at Work Regulations 1999
- The Control of Substances Hazardous to Health Regulations 1999 (COSHH)
20 Appendices

20.1 Appendix 1 - Procedure for manual cleaning

Manual cleaning would normally be carried out using either immersion or non-immersion methods depending on the construction of the device.

20.1.1 Immersion Method

To minimise the risk to personnel undertaking manual cleaning, splashing and the creation of spray must be avoided at all times. Staff carrying out manual cleaning should wear PPE at all times.

1. Fill sink 1 (not a hand basin or other clean receptacle) with potable water to a predetermined level at the specified temperature and with the appropriate detergent. Sink 1 must be solely dedicated for the cleaning of instruments, and not for any other purpose.
2. Detergents used must be specifically designed to clean surgical instruments: washing-up liquid should not be used. Detergent dilution and water temperature should be in accordance with the manufacturer’s instructions and local policy. Consideration should be given to the use of an enzymatic detergent to facilitate the cleaning of surgical instruments with channels or complex parts.

3. Dismantle or open the instrument to be cleaned and fully immerse in the solution to displace trapped air and, in the case of hollow instruments, to ensure penetration of channels.

4. Brush, wipe, agitate, irrigate, jet-wash or hand-spray the item to dislodge and remove all visible dirt, taking care to ensure the item remains under the surface of the water at all times to prevent the creation of aerosol (spray). Brushes should be made from nylon bristles and should be single-use only.

5. If high-pressure-jet guns are used for cannulated instruments, they should be connected to the cold-water supply only. The gun is connected to the instrument and held under water during the irrigation process.

6. Remove the device from sink 1 and drain any excess cleaning solution before placing in sink 2 for rinsing.

7. Change the rinse water after each batch of instruments however the water must be changed if it becomes visibly soiled or cloudy.

8. Rinse the item thoroughly with clean potable water using the water-jet gun when necessary (see point 5).

9. Remove and drain the item, and then dry using the preferred method: for example, by using a clean, non-linting cloth or by mechanical drying. An alcohol wipe MUST NOT be used to facilitate the drying process.
10. Cleaning materials should be safely disposed of in accordance with local waste policy.

11. Record the device that has been processed including the method and solutions used and details of the staff member who completed the procedure.

20.1.2 **Non-immersion method**

This method is appropriate for items whose working components will become compromised by soaking, for example dental drills, power tools or electronic equipment.

Cleaning information about the methods to be used for specific devices must be sought from individual device manufacturers.