DECONTAMINATION OF REUSABLE MEDICAL DEVICES POLICY

During the COVID19 crisis, please read the policies in conjunction with any updates provided by National Guidance, which we are actively seeking to incorporate into policies through the Clinical Ethics Assurance Group

Document Author	Authorised
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Lead Director: Director of Nursing	
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DOCUMENT HISTORY

(Procedural document version numbering convention will follow the following format. Whole numbers for approved versions, e.g. 1.0, 2.0, 3.0 etc. With decimals being used to represent the current working draft version, e.g. 1.1, 1.2, 1.3, 1.4 etc. For example, when writing a procedural document for the first time – the initial draft will be version 0.1)

Date of Issue	Version No.	Date Approved	Director Responsible for Change	Nature of Change	Ratification / Approval
Mar 2012	2.2		Approved	Clinical Governance	Logo and wording updated for new organisation
Aug 2013	3		Rejected	Infection Prevention & Control	Requires significant revision should be led by decontamination lead
Oct 2013	3.1		Decontamination Implementation Group	Ratified at	Decontamination Implementation Group Subject to significant revision
Nov 2013	3.1		Decontamination Lead	Ratified at	Infection Prevention Control Committee
Dec 2013	3.1		Decontamination Lead	Ratified at	Clinical Standards Group
7 Jan 2014	4	7 Jan 14	Decontamination Lead	Approved at	Policy Management Group
Nov 2016	4.1		Executive Director of Nursing and Quality	Policy review	
Nov 2016	4.1		Executive Director of Nursing and Quality	Policy review agreed by	Decontamination Implementation Group (DIG)
25 Nov 2016	4.1		Executive Director of Nursing and Quality	Ratified at	Clinical Standards Group
13 Dec 2016	5.0	13/12/2016	Executive Director of Nursing and Quality	Approved at	Corporate Governance & Risk Sub-Committee
7/11/19	5.1		Executive Director of Nursing	Policy review agreed via email as not quorate at meeting	Decontamination Implementation Group (DIG)
29/11/19	5.1		Director of Nursing	Endorsed at	Clinical Standards Group
19/03/20	6.0	19/03/2020	Director of Nursing	Approved via Voting buttons and Chairs Action at	Policy Management Sub-Committee

NB This policy relates to the Isle of Wight NHS Trust hereafter referred to as the Trust

Contents

1 Executive Summary

This policy provides direction to all staff involved in the decontamination and disinfection of reusable medical devices.

It defines responsibilities in respect of decontamination practice and process and sets out clear standards for assessing which decontamination method is required, with guidance on cleaning and disinfection processes.

2 Introduction

Any equipment used in the diagnosis, treatment, and care of patients, or any other article that comes into contact with patients or their environments, will become contaminated with micro-organisms and may therefore present a risk of infection to others. It is essential that re-useable medical devices are decontaminated to a high standard in order to promote effective patient safety by minimising risk of the transmission of infection.

A wide range of legislation imposes legal obligations on the Organisation with regard to how it manages decontamination processes. Relevant legislation includes the following;

- The Health and Safety at Work Act 1974 and associated Regulations
- The Control of Substances Hazardous to Health (COSHH) Regulations 5th Edition 2002
- HTM 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care (updated July 2016).
- The Health and Social Care Act 2008: Code of Practice for health and adult social care on the prevention and control of infections and related guidance
- HTM 01-06 – Decontamination of flexible endoscopes (updated June 2016)
- Managing Medical Devices (April 2014)
- ISO 13485 and Medical Device Directive 93/42.

3 Definitions

Cleaning: cleaning removes grease, soiling and microorganisms; it is the primary method of decontamination for decontamination of low risk medical devices.

DIG: Decontamination Implementation Group

Disinfection: a process which is intended to kill or inhibit reproduction of pathogenic organisms. It is the second stage of the decontamination process for medium risk items. Disinfectants are not cleaning agents as they may be inactivated by organic material.

HTM: Health Technical Memorandum

IPCC: Infection Prevention Control Committee

IPCT: The Infection Prevention & Control Team

MHRA: Medical & Healthcare products Regulatory Agency

Medical Device: the term “medical device” covers a wide range of products (including surgical instruments, endoscopes, beds and monitors) used in routine healthcare. See 7.1 for more detail.

Sterilisation: a process which renders items completely free of living organisms.
See 7.2 for more detail.

TOE: Trans-oesophageal echocardiogram

TV: Trans Vaginal

TRUS: Trans Rectal Ultra Sound

4 Scope

This policy applies to all healthcare workers in the Trust and to healthcare workers in contracted services, visiting healthcare workers and students.

5 Purpose

This policy gives best practice guidelines on decontamination and disinfection of medical devices, as recommended in national decontamination strategies for the NHS.

6 Roles and Responsibilities

Executive Director of Nursing is responsible for ensuring a policy for decontamination of re-useable medical devices is implemented and that systems are in place for monitoring staff compliance with, and effectiveness of the policy.

The Decontamination Lead should report directly to the Executive Manager (HTM 01-01)

- Organisationally responsible for the effective, and technically compliant, provision of decontamination services.

- Responsible for the implementation of operational policies for decontamination and should ensure specific operational policies are in place for the purchase and decontamination of all medical devices. He/she should ensure that the operational policy clearly defines the roles and responsibilities of all personnel who may be involved in the use installation and maintenance of decontamination equipment.

- Responsible for implementation of the policy and should have a competent understanding of the decontamination of medical devices, guidance legislation and standards.

- May delegate specific responsibilities to key personnel; the extent of such delegation should be clearly set out in the operational policy together with the arrangements for liaison and monitoring.

- Will provide (or seek out) expert, specialist advice regarding all aspects of decontamination within the organisation.

Decontamination Implementation Group (DIG)

- Responsible for ensuring the appropriate facilities, staff and processes within the Trust are in place to minimise risk in the decontamination of equipment, including sterilisation of reusable medical devices, in order to meet the standards required by the Care Quality Commission, The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and other current statutory regulations and guidelines.

The Director of Infection Prevention & Control

- Responsible for overseeing the implementation and impact of this policy
- Will challenge poor practice and will recommend policy and practice changes appropriately.

Head of Facilities

- Responsible for ensuring that decontamination equipment owned by the Trust is properly installed, commissioned, validated and maintained in accordance with relevant statutory standards and guidance, and that all necessary Authorised Persons, Competent Persons, Test Persons and Maintenance Persons are appointed as required by HTM 01-01 and other relevant HTM documents.

The Operational Manager, Hospital Sterilisation & Disinfection Unit (HSDU)

- Responsible for ensuring that local Standard Operating Procedures (SOPs) for decontamination processes within HSDU are compliant with national guidance including ISO 13485 and Medical Device Directive 93/42.

Registration with the MHRA must be maintained on an annual basis, and an external audit must take place by a notified body. Also responsible, in collaboration with the Operational Manager, Estates, for ensuring that equipment within HSDU is maintained, tested and validated in accordance with relevant statutory standards and guidance.

Medical Devices Co-ordinator & Procurement Leads

- Responsible for ensuring that the manufacturers' instructions for decontamination of equipment and devices and any proposed changes to cleaning and disinfection products are reviewed through the Medical Devices/Product Standardisation Groups prior to purchase. This is an essential mechanism to ascertain that relevant experts are consulted appropriately.

- Responsible for ensuring that policies on use of single-use devices, purchase and management of medical devices are in place.

- Responsible for highlighting any issues noted with cleanliness of equipment returned for repair/storage to the relevant department, decontamination lead and IPCT/IPCC.

The Infection Prevention & Control Team (IPCT)

- Responsible for providing advice to Medical Devices/Product Standardisation Groups as appropriate and escalating concerns or issues requiring a higher level of specialist decontamination expertise to the Decontamination Lead or Infection Prevention and Control Doctor as appropriate.

- Responsible for delivering basic verbal instruction/advice on decontamination methods used at ward/department level and will ensure that use of cleaning & disinfection products is included in Infection Prevention & Control compulsory training for clinical staff.

Ward Sisters/Charge Nurses/Community Nurse Leads

- Responsible for ensuring that this policy is disseminated to and implemented by all staff within their department.

- Responsible for ensuring that staff training is commensurate with need for the local area e.g. essential staff training will be very different for HSDU and endoscopy decontamination staff than that of ward level staff.

- Responsible for ensuring that safe systems for handling, storage and use of cleaning products and disinfectants are in place.

- Responsible for maintaining accurate and appropriate Control of Substances hazardous to Health (COSHH 5th Edition 2002) records for their department.

- Responsible for ensuring that, where hazardous chemicals are used, staff health is appropriately monitored in conjunction with Occupational Health services.

- Responsible for ensuring that appropriate personal protective equipment (PPE) is readily available to staff for safe handling of cleaning and disinfectant products.

- Responsible for monitoring decontamination processes in their area and ensure evidence is available that staff are compliant with this policy and other relevant SOPs for decontamination.

All members of staff have a duty to ensure they are familiar with this policy and comply with it in the workplace.

- Must comply with safe systems of work, including guidance within COSHH data sheets regarding handling and use of products

- Must adhere to the manufacturer's instructions for use of cleaning products and disinfectants.

- Must ensure that where risks, accidents or incidents arise in the context of this policy they are appropriately reported.

7 Policy detail/Course of Action

7.1 MEDICAL DEVICE CATEGORIES

The term “medical device” covers a wide range of products (including surgical instruments, endoscopes, beds and monitors) used in routine healthcare. For the purpose of this Policy a Medical Device is defined as follows;
Any instrument, apparatus, appliance, material or health care product (excluding drugs) used for a patient or client for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment or alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control/prevention of Conception/Implantation

The choice of decontamination method for any particular re-useable medical device will depend on the risk associated with the intended use of the device. The risk depends on a number of factors, including the nature of the procedure to be performed on the patient, the susceptibility of the patient to infection and the nature and extent of any possible microbial contamination on the device. Table 1 provides a risk classification and guidance on allocating a device to a risk category

Table 1 – Risk classification for decontamination

Risk Category	Description	Decontamination Method
High risk	Devices in contact with a break in the skin or mucous membrane or to be introduced into a sterile area of the body *e.g. surgical instruments, needles, implants, catheters*	Cleaning followed by Sterilisation
Intermediate risk	Devices in contact with intact mucous membranes, body fluids, known cross-infection risk (e.g. Meticillin Resistant *Staphylococcus aureus* (MRSA), *Clostridiodes difficile (C. diff)*)) or used on highly susceptible patients or sites *e.g. respiratory equipment, clinical thermometers, gastroscopes, TOE/TV/TRUS probes, endoscopes and nasendoscopes*	Cleaning followed by sterilisation or cleaning followed by high level disinfection depending on level of risk
Low risk	Devices in contact with intact	Cleaning in normal

	healthy skin. *e.g. stethoscopes, non-invasive blood pressure cuffs,*	Circumstances

Invasive procedures for patients who have identified risk factors for Prion disease (CJD/vCJD) requires arrangements to be made to reprocess/dispose of instrumentation in accordance with national expert recommendations. Refer to Trust CJD policy.

7.1.1 Endoscopes

Endoscopes (whether heat-stable or heat-labile) are subject to particular procedures for decontamination. Flexible endoscopes (currently excluding flexible nasendoscopes) are re processed in the endoscopy department using automated washer disinfectors.
Rigid scopes are re processed via the Hospital Sterilisation and Disinfection Unit (HSDU). Flexible non-lumened nasendoscopes are currently re processed in the Ear Nose and Throat Department using a manual disinfection process. For further details, please refer to the Endoscope Decontamination Policy and Nasendoscope standard operating procedure (SOP).

7.1.2 Transoesophageal, transrectal and transvaginal ultrasound probes

Semi-invasive ultrasound probes that may come into contact with body fluids and secretions must be used in conjunction with a water-impermeable, single-use, disposable sheath designed for that purpose. These devices are decontaminated using a manual disinfection process. Refer to relevant departmental standard operating procedure (SOP) for guidance.

7.1.3 Surgical Instruments

Reprocessing of re-useable surgical instruments must be carried out in the designated HSDU facility. Use of benchtop sterilisers is not supported within the hospital setting. Use of benchtop sterilisers in an NHS community setting **MUST** have full endorsement of the Trust Board, Infection Prevention & Control Committee and Decontamination Implementation Group (DIG).

7.1.4 Ultrasonic Cleaners may be used prior to further processing in some areas (such as Dental units) for pre-treatment of instruments to remove gross soiling. Ultrasonic cleaners must be maintained and tested in accordance with the relevant Health Technical Memorandum 01-05 including all necessary soil and mechanical function testing.

7.1.5 Traceability

Systems must be in place to fully track and trace all re-useable medical devices used invasively.

Refer to 'HTM 01-01: Management and decontamination of surgical instruments (medical devices)' and 'HTM 01-06 – Decontamination of flexible endoscopes'.

7.1.6 Single Use Devices

Single-use devices must only be used once and must be disposed of in accordance with the organisation's Waste Management Policy following use. Under no circumstances must a single-use device be used more than once. Refer also to the Single-Use Medical Device procedure.

7.1.7 Single Patient Use Devices

May only be re-used again on the same patient in accordance with manufacturer's instructions and must be appropriately decontaminated between uses.

7.2 DECONTAMINATION PROCEDURES General Principles

Advice and guidance should be sought from the Infection Prevention and Control Team and Medical Devices Co-ordinator before purchase of new devices or equipment. This is essential to allow for assessment as to whether the item can be appropriately decontaminated and serviced/repaired if applicable.

7.2.1 Cleaning

Cleaning removes grease, soiling and microorganisms. It is the primary method of decontamination for decontamination of low risk medical devices (see table 1).
Before disinfection or sterilization can be carried out on medium and high risk items, a robust cleaning procedure must also be carried out.

The following general principles must be applied when cleaning medical devices

- All medical devices should be cleaned according to the manufacturers instructions
- For manual cleaning, use a deep sink which is designated for cleaning purposes (not a hand hygiene use sink).
- Wear personal protective equipment (PPE) as appropriate (see Standard precautions – PPE policy)
- Use disposable cloths or single-use detergent wipes, discarding them when they become visibly dirty, dry and after use.
- Where detergent wipes are unavailable or items are being submerged for cleaning, use an approved neutral detergent (Hospec) and warm water (maximum 42-43°C) for general cleaning.
- Rinse items thoroughly in clean water (or with a disposable cloth wrung out in clean water) to remove detergent residue.
- Dry items thoroughly after cleaning using disposable paper roll
- Decontaminate and dry equipment used for cleaning after use
- Store cleaning equipment in a clean and dry area.

7.2.2 Disinfection

Disinfection is a process which is intended to kill or inhibit reproduction of pathogenic organisms. It is the second stage of the decontamination process for medium risk items. Disinfectants are not cleaning agents as they may be inactivated by organic material.

The following general principles must be applied when disinfecting medical devices.

- All items must be thoroughly cleaned prior to disinfection to remove all organic material.
- Only use organisational approved chemical disinfectants (see Appendix A)
- Chemical disinfectants are toxic substances, and the user must comply with the Control of Substances Hazardous to Health (COSHH 5th Edition 2002) regulations. Read the relevant COSHH assessment sheet before using any chemical disinfectant.
- Wear personal protective equipment (PPE) as appropriate. (see Standard precautions – PPE policy). For some disinfectant chemicals or chemical spills this may involve using heavy duty gloves, protective gowns and respirator equipment – check COSHH guidance sheets.
- Ensure adequate ventilation in the area where the disinfectant is used.
- Check the expiry date of the disinfectant and discard safely if out of date.
- Ensure that the correct dilution is used (check manufacturer's instructions).
- Never dilute a disinfectant by guesswork and do not top up disinfectant by adding neat solution after the initial mixing
- Never use two disinfectant agents together.
- Do not add anything to a disinfectant (including detergent) as this may result in a dangerous chemical reaction.
- Ensure sufficient contact time; check manufacturer's instructions
- Rinse items thoroughly after sufficient contact time has elapsed (unless alcohol is used to disinfect, when rinsing is not required).
- Discard disinfectant solution after use in accordance with manufacturers COSHH data.
- Ensure that any bottles or containers used for disinfection are stored in clean, dry condition and are inverted between uses

7.2.3 Sterilisation

Sterilisation is a process which renders items completely free of living organisms. All sterilisation within the St Mary's Hospital site must be carried out in HSDU. Local processing of instruments using Bench Top Sterilisers must not be undertaken without endorsement from Trust

Board, Infection Prevention and Control Committee and the Decontamination lead. All such arrangements must be discussed with the Decontamination Lead and Director of Infection Prevention & Control.

The sterilisation process must be subject to rigorous validation, monitoring and audit processes in accordance with national guidance.

7.2.4 Declaration of Contamination Status Forms

A declaration of contamination status (permit to work/ Medical Equipment Return) (appendix B) must be used when returning any medical device to the Estates or Medical Equipment Management Service (MEMS) for repair or maintenance or when transferring equipment between wards/depts.
Its purpose is to indicate clearly that the device has been thoroughly cleaned prior to transfer and thus is safe for individuals to handle or for re-use on others.
The person cleaning the item MUST be the person completing the form – do not sign on behalf of someone else.

7.2.5 Tagging of Patient Care Equipment

To ensure that it is clear that patient care equipment (e.g. drip stands, monitoring equipment) has been cleaned after use a system of cleaning tags/labels is in place. (See appendix C for Cleaning and tagging of patient care equipment standard operating procedure).

7.2.6 Storage

The guidelines in Table 2 must be followed when storing medical devices:

Table 2 – Storage of medical devices

Physical Conditions	Avoid dirty or wet conditions, inappropriate temperature or humidity. Store away from direct sunlight. There should be sufficient space for safe access.
Storage system	Do not stack too high and do not store heavy items on top shelves. Do not store packages / sterile goods on the floor.
Segregation of equipment	Clean, decontaminated devices awaiting disposal, repair or transfer to other areas are clearly tagged and stored away from potential sources of contamination. Segregate sterile items, equipment, food and non-sterile items away from each other to prevent cross-contamination; ideally equipment and sterile items will be stored in separate storage areas.
Shelf life and stock rotation	Earliest deliveries must be used first to avoid deterioration of stock e.g. rubber components, batteries, sterile product shelf life. Products which have exceeded their expiry date must not be used

Items that have been involved in an incident

In the event of an incident involving a reusable medical device:

1. Inform the Medical Devices Co-ordinator or the duty on-call Medical Electronics Technician out of hours if the incident is deemed to be too serious to wait until the next working day.
2. Immediately quarantine the equipment including any accessories or disposables including packaging if appropriate.
3. Complete incident form.

8 Consultation

This policy has been consulted on by;

- The Medical Equipment Management Service and Medical Device Co-ordinator
- Hospital Sterilisation and Disinfection Unit (HSDU) Manager
- Decontamination Implementation Group
- Infection Prevention & Control Team

9 Training

This policy has a mandatory training requirement which is detailed in the Organisation mandatory training matrix and is reviewed on a yearly basis;

All clinical staff, Estates and Cleanliness personnel are expected to undertake annual compulsory/mandatory update training in infection prevention and control. The IPCT will ensure that all annual programmes of training include guidance on cleaning and disinfection.
It is the responsibility of Departmental Managers to ensure that staff have received the appropriate training and updates in cleaning and disinfection of medical devices appropriate to their role.

10 Monitoring Compliance and Effectiveness

Monitoring implementation of this policy is the responsibility of the Decontamination Lead.

Monitoring of the Cleaning & Tagging of Patient Care Equipment SOP will be undertaken by the Infection Prevention & Control Nursing team as part of the annual environmental audit programme. Results of audit are fed back to the relevant business unit who will be required to devise an action plan to address any areas of non-compliance identified.

Modern Matrons and Ward Sisters will audit against this SOP on a monthly basis to ensure this policy and the SOP is embedded in practice. Results will be fed back through the relevant business unit and an action plan must be devised to address any areas of non-compliance identified.

11 Links to other Organisational Documents

Single use devices procedure

Flexible non-lumened nasendoscope SOP
Ultrasound probe SOP
Transmissible Spongiform Encephalopothies (TSEs) including Creutzfeltd-Jacob Disease (CJD Policy) CJD policy
Use of Personal Protective Equipment
Clean Patient Environment Policy
Care, Decontamination and Maintenance of Endoscopes and Similar Devices Policy

12 References

Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care (updated June 2016). Online at: https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care

HTM 01-06 – Decontamination of flexible endoscopes (updated June 2016). Online at: https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes

ISO 13485 - Quality management for medical devices (2016). Online at: http://www.iso.org/iso/home/store/publication_item.htm?pid=PUB100377

The Control of Substances Hazardous to Health Regulations 5th Edition 2002

The Health and Social Care Act 2008 Code of Practice of the prevention and control of infections and related guidance. July 2015. Online at https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance

13 Appendices

Appendix A

Organisation Approved Disinfectants and their Uses

Preparation	Uses	Areas of use
Alcohol Isopropyl alcohol pre-packed impregnated swabs or wipes (Alcowipes, "sterets")	Disinfection of named items of delicate equipment i.e. lenses	Restricted - Contact Infection Prevention & Control team
2% chlorhexidine in 70% alcohol	PDI CX wipes for hub and port disinfection	Unrestricted
Sodium Dichloroisocyanurate a) Granules (Actichlor/Presept) b) Tablets (Actichlor/Presept) 10,000 ppm 1,000 ppm 125 ppm	Spillage of blood or body fluid (except urine) Treatment of large spillage of blood or body fluid General environmental disinfection Disinfection of infant feeding equipment	All clinical areas
Actichlor Plus Detergent plus Sodium Dichloroisocyanurate tablets	Routine cleaning and disinfection of isolation rooms Terminal (barrier) cleans	All clinical areas
Chlorine Wipes (<Sodium Hypochlorite<1% Anionic Surfactant)	Disinfection of commodes, re-useable bed pan shells, bottle holders and catheter bag stands	Clinical areas using commodes, re-useable bed pan shells, bottle holders and catheter bag stands
Clinell Universal Sanitising wipes	Surface disinfection and cleaning of non-invasive medical devices	Clinical areas as advised by IPCT
Tristel 2 stage process (Duo) **Tristel 3 stage process (Trio)**	Disinfection of skin surface ultra-sound probe for breast procedures Disinfection of Trans-vaginal probes Disinfection of flexible non-lumened nasendoscopes, trans-rectal probe and trans-oesophageal echocardiogram probe	Diagnostic imaging Diagnostic imaging ENT, Cardiology, Day surgery unit
Paracetic Acid	Disinfection of flexible endoscopes	Endoscopy Unit
Hydrogen peroxide vapour	Terminal decontamination of vacated C difficile rooms	Vacated patient environments that can be effectively sealed to prevent leakage e.g. single rooms

Declaration of Contamination Status Form

Medical Equipment Return Form

NHS Isle of Wight NHS Trust

What are you returning? Describe the equipment	
Where has it come from? (Ward/Dept)	
What is the Med Eng Number or serial number?	
Why is the kit being returned? Please tell us what the fault is (if any)	
Your Name – please print	**The Date and Time returned**
Have you cleaned the equipment with yellow Clinell wipes?	
YES ☐ / NO ☐ –if no, what have you used?	

Declaration of Contamination Status Form
Version 06 Issue date: 8.11.2018

Appendix C

Infection Prevention & Control – Standard Operating Procedure (SOP)

Cleaning and Tagging of Patient Care Equipment

1. Purpose

All patient-care equipment must be cleaned after use, to render it safe for handling by staff and re-use by patients.

This SOP sets out clear guidance for cleaning patient equipment after use, whether it is for re-use or prior to storage (whether temporary or longer-term), transfer to other wards/departments and before returning it to the Medical Equipment Management Service.

The SOP also outlines the processes that must be undertaken to ensure that all stored equipment is appropriately tagged/labelled as clean prior to storage.

2. Scope

This guidance applies to **all** equipment used in patient care that is used or stored in wards and departments or may be moved or transferred to other wards or departments.

The term stored will include all items, whether in cupboards, on open shelves or "parked" within wards/bays/corridors that are not for immediate re-use.

Although this guidance is specifically written for wards and departments of St Mary's hospital, the principles will apply to other healthcare settings of all kinds and should be adapted for use therein.

3. Responsibilities

It is the responsibility of every staff member who uses an item of equipment, to ensure it is appropriately cleaned after every use.

The nurse in charge of the ward or department is responsible for ensuring that this SOP is implemented in the workplace and that staff are carrying out cleaning and tagging procedures appropriately.

Modern Matrons are responsible for overall standards of cleanliness within their areas and should routinely check that equipment is clean and has appropriately completed tags.

4. Cleaning equipment after use

This SOP must be used in conjunction with the Infection Prevention & Control Clean Patient Environment policy and method statements for cleaning.

A	Organisation approved detergent wipes (or neutral detergent and water) must be available for equipment cleaning.
B	Disposable cloths (J-cloth or wipes) should be used. A new cloth must be used for each piece of equipment. Do not dip cloths in and out of any detergent solution as this will contaminate it; use a new cloth.
C	Disposable paper roll (blue- or white-roll) must be available for drying each piece of equipment. Failure to dry equipment will trap dust and organisms and leave visible residues.

D	Protective equipment (disposable gloves and apron) should be worn to protect hands from detergent and protect clothing from splashes.
E	Electrical equipment must be disconnected from the mains and care must be taken not to get water/detergent into motors or other electrical components.
F	Ensure mains wires for electrical equipment are cleaned, as are any connecting cables, tubes etc.
G	To clean, use a vigorous action to remove organic matter. Work in a pattern that will draw dirt into one place rather than spread it further across the item.
H	When cleaning rails or bars, work the cloth with a twisting, rotating action that will cover all surfaces of the item. Work in a pattern (left to right or right to left) which will draw dirt and organisms to one place before removal.
I	Dispose of all cleaning cloths in a black bag. Dispose of protective equipment in an orange bag. Wash hands thoroughly.
J	After the cleaning process, carry out a visual check to make sure the item is completely clean. Remember to check the underside as well as top surfaces.

5. Tagging/labelling of cleaned equipment

All cleaned items must have a self-adhesive tag completed and attached securely to the item in such a way that the item cannot be re-used without removing the tag. This tag must include details of the ward/department, date and time of cleaning and the name of the person who has cleaned the item.

Any item that is not tagged will be presumed to be dirty and must not be used, transferred to another area, placed in storage cupboards or in open storage areas until it has been thoroughly cleaned.

Porters are not permitted to collect or transfer untagged (dirty) items from wards/departments.

In addition to the tag, items for return to the Medical Equipment library or Medical Electronics/Estates Maintenance department must have a completed "Declaration of Contamination Status/Permit to Work" form. Items that do not have a tag AND form, will not be collected by Porters or Medical Equipment Library staff until they are cleaned and tagged.

Note: Tags MUST be removed when an item is returned to use.

6. Tag types

Green, self-adhesive tape or notelet tags;

These tags are designed for short-term, temporary use and as such, will be in common use in all wards and departments, for routine labelling of items that have been cleaned after use. All tags must be completed clearly, with ward/department name plus the name of the person cleaning the item and the date it was cleaned.

Notelet-type tags are only suitable for flat surfaces or placing within a flat area, as they have low adhesive strength and will fall off if used on contoured surfaces.

Self-adhesive tags must be applied in such a way that the item cannot be re-used without removing the tag. ***Tags must be removed and discarded when the item is returned to use.***

Yellow Tyvek tags;
These tags are stronger than the green tape and are therefore more suitable for items that will remain in longer term storage or that will be transferred from one area to another. ***Tags must be removed and discarded when the item is returned to use.***

Yellow tags should be used, after cleaning, for items being transferred from department to department or to the Medical Equipment Library.

For community equipment, yellow tags may be used for storage of clean items and for return of cleaned items to the Integrated Community Equipment Service store.

7. Returning an item to use

When preparing to re-use a tagged item, always check the item thoroughly to ensure it is actually clean. If the tag indicates it was cleaned more than 48 hours ago, it should be cleaned again to remove any dust or contaminants.

Wherever possible, remove the cleaning tag at the patient bedside; this clearly indicates that the item you are bringing to them is clean.

Under no circumstances must a tag be left in place while the item is in use. During equipment cleanliness audits, if tags are found on in-use items the area will automatically fail that audit.
(The rationale for this decision is that if tags are left in place, there is scope for multiple use without cleaning the item, with the additional drawback that the individual named on the label may then be mistakenly accused of not cleaning the item properly.)

Appendix D

Financial and Resourcing Impact Assessment on Policy Implementation

NB this form must be completed where the introduction of this policy will have either a positive or negative impact on resources. Therefore this form should not be completed where the resources are already deployed and the introduction of this policy will have no further resourcing impact.

Document title	Decontamination of Reusable Medical Devices policy

Totals	**WTE**	**Recurring £**	**Non Recurring £**
Manpower Costs			
Training Staff			
Equipment & Provision of resources			

Summary of Impact:

Risk Management Issues: No change
Benefits / Savings to the organisation: No change

Equality Impact Assessment

- Has this been appropriately carried out? YES/
- Are there any reported equality issues? NO

If "YES" please specify:

Use additional sheets if necessary.

Please include all associated costs where an impact on implementing this policy has been considered. A checklist is included for guidance but is not comprehensive so please ensure you have thought through the impact on staffing, training and equipment carefully and that ALL aspects are covered.

Manpower	**WTE**	**Recurring £**	**Non-Recurring £**
Operational running costs			
Totals:			

Staff Training Impact	**Recurring £**	**Non-Recurring £**
Totals:		

Equipment and Provision of Resources	**Recurring £ ***	**Non-Recurring £ ***

Accommodation / facilities needed		
Building alterations (extensions/new)		
IT Hardware / software / licences		
Medical equipment		
Stationery / publicity		
Travel costs		
Utilities e.g. telephones		
Process change		
Rolling replacement of equipment		
Equipment maintenance		
Marketing – booklets/posters/handouts, etc		
Totals:		

- Capital implications £5,000 with life expectancy of more than one year.

Funding /costs checked & agreed by finance:	
Signature & date of financial accountant:	
Funding / costs have been agreed and are in place:	
Signature of appropriate Executive or Associate Director:	

Appendix E

Equality Impact Assessment (EIA) Screening Tool

Document Title:	Decontamination of Reusable Medical Devices policy
Purpose of document	Guidance for staff on Decontamination
Target Audience	All Staff involved with Use of or Management of Medical Devices
Person or Committee undertaken the Equality Impact Assessment	Hilary Male/Decontamination Implementation Group

1. To be completed and attached to all procedural/policy documents created within individual services.

2. Does the document have, or have the potential to deliver differential outcomes or affect in an adverse way any of the groups listed below? NO

   If no confirm underneath in relevant section the data and/or research which provides evidence e.g. JSNA, Workforce Profile, Quality Improvement Framework, Commissioning Intentions, etc.

   If yes please detail underneath in relevant section and provide priority rating and determine if full EIA is required.

		Positive Impact	Negative Impact	Reasons
Gender	Men			
	Women			
Race	Asian or Asian British People			
	Black or Black British People			
	Chinese people			
	People of Mixed Race			
	White people (including Irish people)			

	People with Physical Disabilities, Learning Disabilities or Mental Health Issues			
Sexual Orientation	Transgender			
	Lesbian, Gay men and bisexual			
Age	Children			
	Older People (60+)			
	Younger People (17 to 25 yrs)			
Faith Group				
Pregnancy & Maternity				
Equal Opportunities and/or improved relations				

Notes:
Faith groups cover a wide range of groupings, the most common of which are Buddhist, Christian, Hindus, Jews, Muslims and Sikhs. Consider faith categories individually and collectively when considering positive and negative impacts.

The categories used in the race section refer to those used in the 2001 Census. Consideration should be given to the specific communities within the broad categories such as Bangladeshi people and the needs of other communities that do not appear as separate categories in the Census, for example, Polish.

3. Level of Impact

If you have indicated that there is a negative impact, is that impact:		
	YES	**NO**
Legal (it is not discriminatory under anti-discriminatory law)		
Intended		

If the negative impact is possibly discriminatory and not intended and/or of high impact then please complete a thorough assessment after completing the rest of this form.

3.1 Could you minimise or remove any negative impact that is of low significance? Explain how below:
3.2 Could you improve the strategy, function or policy positive impact? Explain how below:
3.3 If there is no evidence that this strategy, function or policy promotes equality of opportunity or improves relations – could it be adapted so it does? How? If not why not?

Scheduled for Full Impact Assessment	Date: 2/11/16
Name of persons/group completing the full assessment.	Hilary Male//Decontamination Implementation Group
Date Initial Screening completed	