The Royal Wolverhampton NHS Trust

HS12
Decontamination of Re-usable Medical Devices Surgical Instruments and Scopes

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1.0 Policy Statement

The purpose of this Policy is to ensure the Trust has systems in place for decontamination which complies with the relevant provisions of the basic code to minimise the risk of Healthcare Associated Infection (HCAI) to patients, staff, and visitors.

The policy aims to:

- Promote the safest possible environment for patients through the identification and application of best practice in the decontamination of re-usable medical devices.
- Provide compliant guidance to all staff who undertake the decontamination of re-usable medical devices within the Trust.
- Provide guidance to staff in selecting the most appropriate method of decontamination for re-usable medical devices based on the level of risk.
- Promote consistency in decontamination practices across the Trust.

This policy covers decontamination for all medical devices excluding surgical instrumentation. Within this policy decontamination of medical devices will fall into the following categories:

- Flexible Endoscopes
- Dental Instruments
- Medical Devices – Devices used for diagnosis and/or treatment of disease, for monitoring patients, and as assistive technology and does not include general workshop tools or general-purpose laboratory equipment.

This policy defines the requirements of implementing for the decontamination programme across the Trust sites and Community Dental Services.

- Decontamination of re-usable medical devices taking place in appropriate dedicated facilities (defined later in policy).
- Appropriate procedures are used for the acquisition and maintenance of decontamination equipment.
- The purchase of new equipment is compatible with the Trust's decontamination processes.
- Staff are trained in decontamination processes and hold appropriate

competencies for their role.

- There is a monitoring system in place to ensure decontamination processes are fit for purpose and meet required standards.

In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict-of-Interest Policy is to be considered the primary and overriding Policy.

2.0 Definitions

Cleaning	Cleaning physically removes, but does not necessarily destroy, infectious agents and the organic matter on which they thrive. The reduction of microbial contamination depends upon many factors, including the effectiveness of the cleaning process and the initial bio burden. Cleaning is an essential pre-requisite to ensure effective disinfection or sterilisation.
Contamination	The soiling or pollution of inanimate objects or living material with harmful potentially infectious or other material; this is most likely to be organic matter and infectious agents but may also include other undesirable substances e.g., chemical residues. Such contamination may have an adverse effect on the function of a medical device and may be transferred to a person during or subsequent processing and storage.
Decontamination	Decontamination removes or destroys contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities, to initiate a harmful response. Differing levels of decontamination are used depending on the device and the procedure involved. The levels of decontamination are either cleaning followed by high level disinfection or cleaning followed by sterilisation.
Disinfection	A process used to reduce the number of viable infectious agents. Some pathogens may not be inactivated, e.g., certain viruses and bacterial spores. Disinfection does not achieve the same reduction in microbial contamination levels as sterilisation.
Single use	Should be used once and discarded. Should be used for single patient use only and must not be reprocessed or re-used under any circumstances.
Sterilisation	A process used to render an object free from any viable infectious agents including viruses and bacterial spores.

3.0. Accountabilities

3.1. Decontamination Group

The Decontamination Group is accountable to the Infection Prevention and Control Group (IPCG), that is directly accountable to the Quality Governance Assurance Committee.

Decontamination Group is required to provide reports to the IPCG on all activities, risks, and issues on decontamination.

Provide strategic direction for the prevention and control of healthcare associated infections (HCAI) for the organisation in line with decontamination principles and practices.

3.2. Chief Executive Officer

The Chief Executive is responsible for Trust Wide compliance with all Decontamination Regulations of surgical instruments and flexible endoscopes used by the Trust in line with Department of Health guidance. The Chief Executive will designate a nominated Decontamination Lead with organisational responsibility for the effective and fully comply with national guidance.

3.3. Decontamination Lead

The Decontamination Lead is responsible for the implementation of the operational policy for decontamination; ensuring arrangements for compliance are in place, taking account of best practice, national guidance, and monitoring the decontamination processes put in place.

3.4. Authorised Person (Decontamination) (AP (D)) Estates

The AP (D) is responsible for the engineering aspects of decontamination.

3.5. User

This person is designated by service areas to be responsible for the management of the decontamination process within their localised areas.

3.6. Operator

Any person with the authority and trained to operate a washer disinfector or steriliser, in line with local procedures.

3.7. Competent Person (Decontamination) (CP (D))

The CP (D) is responsible for carrying out maintenance, validation, and periodic

testing of decontamination equipment.

3.8. Microbiologist (Decontamination)

Designated by the Trust to be responsible for advising the User on microbiological aspects of disinfection and sterilisation of non-medical products.

3.9. Authorising Engineer (Decontamination) (AE (D)) - External

The Trust contracts this person to provide independent auditing and advice on all aspects of the decontamination process, including washer disinfectors, sterilisers, sterilisation, and validation.

3.10. Senior Sisters/Charge Nurses/Managers/Department Leads

Must ensure that this policy and its associated procedures (see below) are fully adhered to by all staff working within their area of responsibility:

- Ensure this policy is available to all staff working in this area of responsibility.
- Ensure staff are aware of, and implement, correct practice in the decontamination of re-usable medical devices.
- Ensure no re-usable medical devices are purchased or trialled unless cleaning/decontamination instructions are available have been reviewed and approved by the Trust Decontamination Lead.
- Ensure devices designed as 'single use only' ② are never re-used;
- Ensure medical devices have been assessed and appropriate levels of decontamination have been identified.
- Ensure that their staff are appropriately trained in the decontamination of medical devices and that decontamination of medical devices is undertaken in line with the Trust and local policies, procedures, and protocols.
- Ensure that prior to use, reusable medical devices that are loaned for use within the Trust, have an assessment undertaken to establish whether the device can be appropriately decontaminated, prior to use, using existing methods currently used within the Trust.
- Ensure adequate provision of disinfectants, cleaning agents and equipment necessary to achieve the required standard of decontamination.
- Provide appropriate environmental conditions for the decontamination of medical devices.

3.11 Staff

Staff in identified areas who are involved in the use, inspection, service, repair or transportation of medical devices will co-operate and assist with the

implementation of this Policy and its associated procedures. The following procedures are to be undertaken.

- Responsible for recording details of the decontamination (including cleaning) of medical devices/equipment where this has been undertaken.
- Bring to the notice of their Line Manager any problems or failings associated with the decontamination process.
- Undertake appropriate training courses/programmes as required, including induction and training associated with the decontamination process.
- Promptly report all incidents concerning the decontamination process to their Line Manager in accordance with the Trust's policy and procedure for reporting incidents.
- Report any adverse ill health effects arising from the decontamination process to their Line Manager, the Health & Safety Department and the Occupational Health and Wellbeing Department.
- All staff undertaking decontamination duties must report any adverse incident, concerning any aspect of the decontamination process, in line with Trust Policy OP10.

3.12. Infection Prevention Team

Responsible for providing the following support:

- Advice on potentially difficult areas to clean, e.g., dust traps etc.
- Assist in and do risk assessments as required.
- Investigate areas of special risk to give advice on safe practice.
- Audit practice and monitor standards in line with current legislation and guidance.

3.13. Procurement Department

Will ensure that prior to the purchase of any reusable medical devices, an assessment is undertaken, and are in line with products that are UK validated.

3.14. Sterile Services Provider

To provide decontamination services in compliance with current legislation and guidelines and provide specialist advice on decontamination and sterilisation as appropriate.

- Ensure full compliance with ISO 13485:2016/EN ISO 13485:2016 and Regulation 14 of the UK MDR 2002.
- Ensure that the department is subject to external audit from a registered notified body and undertake any corrective actions deemed necessary.

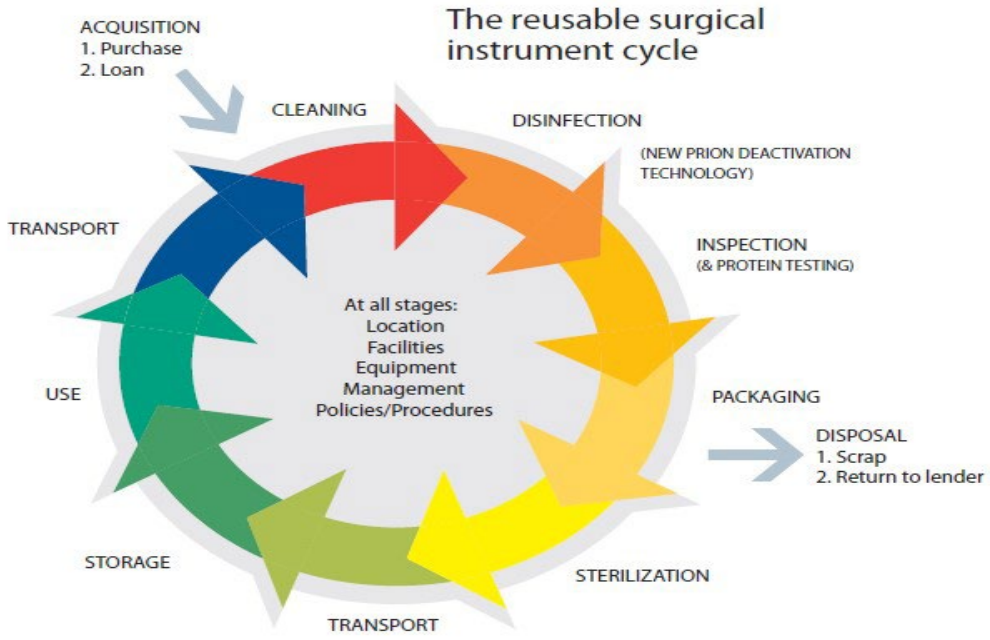
3.15. Health Safety & Improvement Coordinator

To advise on the suitability from a Health and Safety perspective and will issue alerts received from the MHRA as appropriate.

4.0. Policy Detail

The process for decontamination must incorporate all elements of the National Decontamination Programme which is indicated below in figure 1. This is the decontamination cycle, which allows healthcare workers involved in particular areas of decontamination to focus on as set out in HTM 01-01 guidance.

figure 1



4.1. All areas must adopt the essential standards in the decontamination of medical devices and equipment. ***Attachment 1*** sets out the requirements for cleaning, labelling, transportation, storage, compatibility requirements, record keeping and tracking and traceability.

4.1.1. All areas that undertake local decontamination of medical devices must have written procedures/protocols in place to include manual cleaning, disinfection / sterilisation, and storage / transport.

4.1.2. All areas that have equipment for the decontamination of medical devices must have in place a procedure for the routine testing and maintenance of this equipment, in line with manufacturer's recommendations. This will include, where necessary, daily, weekly, quarterly and annual testing and maintenance.

4.2. All areas that use reusable medical devices must have procedures in place to ensure effective decontamination of those devices in between patient episodes. The

choice of decontamination method will rely on a number of factors (see ***Attachment 2 Classification of Infection Risk associated with the Decontamination - Assessment Matrix)*** including:

- Risk to patients and staff from equipment.
- Micro-organisms involved.
- Type of device to be decontaminated.
- Level of decontamination required.

4.3. **All** surgical instruments used within the Trust **MUST** be decontaminated within the contracted Sterile Services Department (SSD).

SSD, where decontamination of surgical instruments occurs, will have written procedures in place. All parts of the decontamination process of surgical instruments must be traceable, including to the patient they are used on; this will include local decontamination, with records being kept.

All staff that have decontamination duties within SSD will be appropriately trained on all procedures to be followed, including the use of decontamination equipment.

4.4. All areas must ensure that decontamination of medical devices is in line with HTM 01- 06, this is further detailed in the Appendices to this policy.

Flexible Endoscopes ***(Attachment 3)***

Dental Instruments **(Attachment 4*)***

4.5. Measures to be taken with known or suspected CJD and vCJD are set out in Trust *Policy IP21 TSE/CJD.*

4.6. All areas must ensure that there is a system in place to ensure they can be traced through all levels of the decontamination process and to each patient. ***Traceability records must be kept.***

4.7. Procurement is used to ensure a Pre-Acquisition Questionnaire (PAQ) is issued to prospective suppliers/manufacturers of medical equipment and for obtaining a completed PAQ form prior to the trial or purchase of medical devices/equipment. Once returned, the completed questionnaire will be sent to the Trust Decontamination Lead for assessment and agreement in terms of compatible decontamination processes before trial or purchase takes place (see **Attachment 5** ***for*** PAQ and **Attachment 6** to be completed by the providing company to establish that the device can be appropriately decontaminated using existing methods currently used within the Trust and in line with the manufacturer's guidance).

4.8 The Trust will continually review and develop practices in order to comply with all present and future medical device legislation within resources available.

4.9. The Trust will undertake risk assessments of the environmental conditions in all locations where the decontamination of medical devices is undertaken.

4.10. The Trust will undertake risk assessments on all processes utilised in the decontamination of medical devices. The outcomes of all medical device risk assessments will be presented to the Decontamination Group.

4.11. SSD will report any significant or major decontamination incidents to the Decontamination lead, who will liaise with Infection Prevention, Health & Safety, the MHRA and where appropriate to the Executive responsible for Decontamination and to the Decontamination Group.

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	No
2	Does the implementation revenue resources of this policy require additional	No
3	Doe the implementation of this policy requires additional manpower	No
4	Does the implementation of this policy release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments	

6.0 Equality Impact Assessment

The policy has been assessed and does not affect the equality and diversity of any one particular group of stakeholders.

7.0 Maintenance

The Decontamination Working Group will maintain this policy to ensure that it reflects up-to-date practices.

8.0 Communication and Training

This policy is located on the Trust intranet. Senior Sisters/Charge Nurses/Managers and Matrons will be informed of the launch of the updated Policy.

Service leads must ensure that all appropriate staff have been apprised of their responsibilities as described in the policy.

Appropriate training is to be provided for all staff who undertake the decontamination of

instruments and endoscopes. The training of staff must be recorded and reviewed on an annual basis by the directorate/service managers.

9.0 Audit Process

Regular audits of the processes applied in the decontamination of medical devices will be undertaken with outcomes being reported to Decontamination Group (DG).

Criterion	Lead	Monitoring method	Frequency	Group
HTM 2010 (AWD) Automated Washer Disinfector (AWD) Areas having AWD.	Estates – Trust Authorised Person	Brush Test for proteins and TVC of micro-organising and productivity. FULL audit including training records, traceability records, maintenance records.	Test weekly if adverse > IPCG Otherwise QTR Annual	DG
CQC Regulation 15 Premises and Equipment (specifically **15(2)** The registered person must, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purposes for which they are being used)	Decontamination Lead	Surgical Instruments – SSD Endoscopy instruments via AWD process Manager database system.	QTR QTR	Medical Equip Group
CQC Fundamental Standard Regulation 15 Premises and Equipment	Medical Physics	Maintenance records	Annual	Medical Equip Group

Technical Audits (equipment that is not sent to SSD or decontaminated in an AWD)	Hotel Services	Observational	Monthly	DG
HTM 01-05 Decontamination in primary care/community dental practices	Lead for Community Dental Services	Audit of manual cleaning protocol and automated decontamination on protocol for Provider dental services	Annual Audit	DG
JAG Accreditation	Endoscopy services lead & AE(D)	JAG Annual review of flexible endoscopies – decontamination facilities.	Annual	Service Governance group
External Audits will be undertaken by the Approved Engineer (AE/D) in line with current standards, including HTM's, MHRA guidance and Standards for Better Health	Service Leads with AE(D)	Observational/set audit review.	As and when in line with new/updated guidance changes.	DG

10. References

- MAC Manual - Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health. MHRA.
- Decontamination of surgical instruments (HTM 01-01) – June 2016
- Management and decontamination of flexible endoscopes (HTM 01-06) – June 2016
  https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attach ment_data/file/530418/HTM0106_PartA.pdf
- Single use medical devices – Implications & Consequences of re-use. MHRA
- Managing Medical Devices V1.3 Jan 2021 MHRA Safeguarding public health (publishing.service.gov.uk)
- Benchtop Steam Sterilizers - Guidance on Purchase, Operation and
- HTM 01-05 (2013) Decontamination in Primary Care Dental Practices
- EU Medical device regulators May 2020 (MDR 2020)
- Updated Medical Devices Regulations 2002 (reviewed Nov 2022), following the end of the Brexit period.

Policy number and Policy version: HS 12 v7	Policy Title Decontamination of Re-usable Medical Devices Surgical Instruments and Scopes	Status: Final	Author: Trust Decontamination Lead Chief Officer Sponsor: Chief Operating Officer
Version / Amendment History	**Version**	**Date**	**Reason**
	1	Oct 2006	Trust Decontamination Lead
	2	Feb 2008	Trust Decontamination Lead
	3	Sept 11	Trust Decontamination ion Lead
	4	Jan 2013	Trust Decontamination Lead
	4.1.	Oct 2013	Trust Decontamination Lead
	5.0.	Sept 2016	Trust Decontamination Lead
	5.1	Sept 2019	Head of Emergency Preparedness
	5.2	April 2020	Head of Emergency Preparedness
	6	July 2020	Head of Emergency Preparedness
	7.0	July 2023	Full review
Intended Recipients: All Clinical areas, and areas that deal with decontamination of medical devices.			
Consultation Group / Role Titles and Date: Decontamination Group 9 May 2023, Clinical Teams, across the Trust, including Cannock Chase Hospital, Community Dental Services and Medical Physics & Clinical Engineering			

Name and date of Trust level group where reviewed	Trust Policy Group August 2023
Name and date of final approval committee	Trust Management Committee September 2023
Date of Policy issue	September 2023
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	August 2026

Training and Dissemination: The approved policy can be found on the Trust intranet site. Senior Managers and Matrons will be informed of the launch of the updated policy via the communications department.

To be read in conjunction with:

- HS11 The Management of Medical Devices and new EU regulations for Medical Devices (MDR) in May 2020.
- IP08 Infection Prevention Operational Policy
- IP19 Blood and Body Fluid Spillage Management
- IP01 Hand Hygiene Policy
- IP04 Transportation of Clean and Contaminated Instruments, Equipment and Specimens.
- IP21 Control and management of Transmissible Spongiform Encephalopathies including Creutzfeldt Jacob Disease (CJD)
- Cleaning Strategy Version: 5 September 2021 http://intranet.xrwh.nhs.uk/pdf/policies/ST_Cleaning_Strategy.pdf

Initial Equality Impact Assessment (all policies): YES
Impact assessment (as required): NA

Monitoring arrangements and Committee	**Trust Decontamination Group**

Document summary/key issues covered.

This policy covers the decontamination for all medical devices excluding surgical instrumentation which is decontaminated by SSD provider (Section 4). This sets out the requirements of implementing a decontamination programme across the Trust's sites and community dental services, ensuring:

Decontamination of re-usable medical devices, surgical instruments and scopes taking place in appropriate dedicated facilities outlined in the policy.

Appropriate procedures are used for the acquisition and maintenance of decontamination equipment and the purchase of new equipment is compatible with the Trust's decontamination processes.

Staff are trained in decontamination processes and hold appropriate competencies for

their role.	
Key words for intranet searching purposes	Decontamination

Attachment 1

Essential standards in the decontamination of medical devices and equipment.

1.0. Health Technical Memorandum (HTM 01-06)

All medical devices requiring sterilisation or high-level disinfection are decontaminated in compliant facilities that are designed for the purpose of decontaminating medical devices through validated processes, systems and controlled environment conditions to ensure that all potential environments, cross infection, handling and medical device usage risks are minimised.

Low risk items (e.g., infusion devices) are cleaned in designated areas of ward/clinics etc. in accordance with the processes within this policy.

1.1. Cleaning

In order to decontaminate medical devices effectively, irrespective of whether disinfection and/or sterilisation is required, all organic debris (e.g., blood, tissue, and other body fluids) must be removed from the item prior to disinfection and/or sterilisation. Effective cleaning of medical devices prior to disinfection or sterilisation is of the utmost importance in reducing the risk of transmission of infectious agents.

1.1.1. Automated washing methods are preferred to manual cleaning, which can be controlled and validated. All items that are suitable for automated cleaning must be processed within SSD.

1.1.2. When manual cleaning is the only option, follow the decontamination assessment matrix in ***Attachment 2***, which gives examples of when this process can be considered.

1.1.3. Manufacturer's instructions must be followed for all elements of the decontamination process. Where advised in the manufacturer's instructions, items must be dismantled before cleaning. This will allow for all areas of the item being cleaned to be accessed during the decontamination process. The manufacturer's instructions must be retained in all areas where medical equipment is cleaned.

1.2. Labelling

Following decontamination, medical devices must be labelled as follows:

- Items decontaminated within SSD must be labelled after sterilisation with a label that is fully compliant with MDD93/42/EEC.

- Items decontaminated in an Automatic Endoscope Washer (AEW) that are not identified for immediate patient use must be placed in storage cabinets with print outs of the processing cycle attached. When transported for patient use, each endoscope must be laid in a tray identified for the purpose and be delivered to the treatment room together with the processing data print out. The tray must be enclosed with a purpose specific cover during transportation.

Decontaminated medical devices and equipment prior to service or repair for return to the Clinical Engineering Equipment Library (CERL)/other Clinical Engineering workshop must be labelled with a "Green is clean" label and, where appropriate, with a certificate of decontamination (e.g., where an item is to be sent for service/maintenance/repair or disposal).

NB. Contaminated medical devices must <u>not</u> be sent via internal or external post.

1.3 Transportation

Equipment and other medical devices including instruments must be transported so as to prevent microbial contamination or damage and protect the individual transporting them.

Containers used for transportation must be suitable for purpose, rigid, enclosed and easily decontaminated for re-use. Any inserts for supporting the device must also be easily cleaned.

Records of which items of equipment are transported, on what date, by whom, and between which locations must be made and retained for audit.

1.4. Storage

The environmental conditions of the area designated for storage and distribution must ensure the integrity of all materials and products i.e., be clean, well-ventilated, and secure. The accommodation must afford adequate protection to prevent contamination or deterioration of the product. Records must be made detailing dates and identify of items entering and leaving storage areas. Checks of expiry dates of decontamination items must also be undertaken at regular intervals in order that those items that require to be decontaminated again can be identified, removed from stock, and be sent for subsequent decontamination.

1.5. Compatibility

Personnel responsible for reprocessing reusable medical devices must always follow the manufacturer's instructions.

The decontamination agents (detergents, water, including ultrasonic activity where utilised) that are used must be compatible with both devices and reprocessing equipment.

Staff must consult the medical device and reprocessing equipment manufacturer/supplier before changing any decontamination processes.

Decontamination of reusable medical devices must be done in accordance with the instructions provided by the device manufacturer.

Staff must ensure that appropriate decontamination facilities and compatible agents are available before purchasing new devices (see ***Attachment 5*****).**

1.6. Record Keeping

The Consumer Protection Act 1987 and in particular product liability has implications for the processing of devices used for patient care. It is essential to maintain adequate records that demonstrate how a particular device was processed. This includes a description of the methods employed together with details of available trained personnel with copies of training records. The Trust must have the ability to demonstrate how instruments and equipment have been processed through the decontamination cycle.

For surgical instruments and endoscopes, records must be maintained and retained to enable instruments to be traced to individual patients.

1.7. Tracking and Traceability

Medical devices that are used in surgery or invasive procedures that are decontaminated must be traceable through the decontamination process and to the patient that they are used on. Therefore, it is important that the relevant records must be maintained for all the medical devices cleaned, identifying:

- the cleaning and sterilisation method used.
- the name of the person undertaking the decontamination.
- details of the actual item being processed.
- training records of the person undertaking decontamination.

This information is required so that medical devices can be traced, if required, in

the event of a failure in the decontamination cycle or for infection control reasons. Records relating to decontamination processes must be maintained by each Ward/Department where decontamination occurs.

Attachment 2

Classification of Infection Risk Associated with the Decontamination of Medical Devices Decontamination Assessment Matrix

The choice of decontamination method may be related to the infection risk associated with the intended use of the equipment. Other factors that must be considered include:

1. The nature of the contamination
2. The time required for processing.
3. The heat, pressure, moisture, and chemical tolerance of the object
4. The availability of the processing equipment
5. The quality and risks associated with the decontamination method.
6. The manufacturer's guidance

Risk Category	Patient Contact	Decontamination Level	How	Examples of Equipment
HIGH	Break in skin or mucous membrane or medical devices introduced into a sterile body cavity.	Sterilisation or Single Use Item	Steam Single use item-dispose of after use.	Surgical instruments
HIGH	Close contact with intact mucous membrane. Bodily fluids or particular virulent or readily transmissible microorganisms. Highly susceptible patient or site.	Sterilisation or Disinfection	Steam (preferable) Chemical disinfectant (if heat not suitable)	Endoscopes
LOW	Contact with normal and intact skin.	Cleaning	Water with Detergent	Mattresses
MINIMAL	Items not used in close contact with patient or their immediate surroundings.	Cleaning	Water and Detergent	Walls and floors

DECONTAMINATION OF FLEXIBLE ENDOSCOPES

To be read in conjunction with IP21 TSE/CJD Policy & definitive UK guidance for decontamination of flexible endoscopes and TSE infection control.

1. Decontamination of flexible endoscopes is undertaken in the following areas:

- Endoscopy Unit, Beynon Centre, New Cross Hospital Nucleus Theatres, New Cross Hospital.
- Urology OPD, New Cross Hospital.
- Head & Neck OPD (non-lumen), New Cross Hospital.
- Endoscopy unit, Cannock Chase Hospital.

2. The decontamination of flexible lumen endoscopes **must** take place in an Automated Washer Disinfector (AWD).

3. All areas that decontaminate flexible endoscopes **must** have written local procedures in place to outline the full decontamination process that must include: -

- Scope preparation prior to cleaning.
- Manual cleaning process.
- AWR disinfection process.
- Post disinfection check of flexible endoscope.
- Storage.

4. Neutral detergent must be used on flexible endoscopes during the manual cleaning process.

5. Each decontamination process of flexible endoscopes **must** be traceable including the scope used on individual patients. Records **must** be kept.

6. All equipment that is used to decontaminate flexible endoscopes **must** be subject to routine maintenance and testing, in line with manufacturer's recommendations, on a daily, weekly, quarterly, and annual basis.

7. All staff who undertake decontamination **must** be appropriately trained on all procedures to be followed, including the use of decontamination equipment.

Attachment 4

Decontamination in Primary Care Dental Service

By March 2007 the Department of Health "National Decontamination Programme 2005" was required to be implemented. This document outlined standards for decontamination of instruments in Primary Care. Information is available online www.dh.gov.uk .

Manual decontamination of instruments is no longer recommended (ref: DH NDP2005).

Four options were outlined:

1. Single use items/devices.
2. Central Sterile Service Departments (CSSD).
3. Accredited localised automated decontamination.
4. A combination of 1 and 2.

Dental services have been given separate decontamination guidance in HTM 01-05 Decontamination in Primary Care Dental Services (2013). This includes single use items and accredited localised automated decontamination.

Single use items

Single use items must only be used on an individual patient and must not be re-used. The symbol below is used to identify single use items, all dental staff must be aware of its meaning.

Examples of single use items used within the dental department include scalpel blades, aspirator tips, 3 in 1 syringe tips, headpiece covers, steel burrs, mouthwash wash cups and applicator brushes once used these items must be disposed of in suitable clinical waste receptacles.

Staff Training

All dental staff must be aware of the procedures required to prevent the transmission of infection and must understand why these procedures are necessary.

Members of staff undertaking decontamination must be competent, properly trained in all relevant procedures and supervised. The line manager must hold training records.

All new staff must be appropriately trained in Infection Prevention procedures on induction and prior to working in the department. A record of staff training must be kept for auditing purposes.

Accredited Localised Decontamination

This option is used by the Special Care Dental Service and as per HTM 01-05 recommendations uses separate rooms to achieve best practice.

The rooms are laid out to facilitate a dirty to clean flow. Instruments are first processed in an automated washer disinfector that complies with HTM 01-05 and is fully validated. Following this they are checked to ensure all debris is removed and sterilized using a bench top autoclave (type N), they are then bagged and dated.

Deep sinks are in place to facilitate manual cleaning in the short term if there is a breakdown of washer disinfectors, the Trust has spare autoclaves in place and quick replacement is possible should an error show on the autoclave.

Support for this process takes place via an internal and an external authorised engineer to ensure compliance. The dental service audits process quarterly. The dental service does not track and trace instruments this is not a current requirement of HTM 01-05.

Cleaning Procedures

Effective cleaning of dental instruments before sterilisation is of the utmost importance to reduce the risk of transmission of infectious agents.

Research shows that instruments cleaned as soon as possible after use are more easily cleaned than those left for a number of hours before reprocessing. If it is impossible to process instruments quickly, e.g., following a session on the mobile dental unit, an enzyme spray must be used to improve protein removal and improve the overall decontamination process. Instruments waiting to be decontaminated must be stored in a designated lockable dirty area. If instruments have to be transferred from the point of use to a decontamination area a suitable washable lidded plastic container must be used.

Manual Cleaning of Instruments.

For dental services manual cleaning will only be used if there is an equipment breakdown. At all other times the automated process must be followed.

Compared with other cleaning methods, manual cleaning presents a greater risk of inoculation injury to staff. However, despite the limitations of manual cleaning it is important for each department to have the facilities, documented procedures and trained staff for when other methods are not available.

Washer Disinfectors-Automated Process.

Automated cleaning methods provide an efficient, reproducible process which can be easily controlled and validated. It also provides protection for the user; therefore, manual cleaning of instruments must only be taken as a last resort or if automated cleaning of devices in contra indicated.

Each stage of the decontamination process will reduce the bio burden on the device being processed. Washer disinfectors are used to carry out the cleaning and disinfection in an automated cycle. The cycle has four stages.

- Flush-removes difficult contamination, blood, and tissue.
- Wash-removes remaining soil.
- Rinse-removes detergent.
- Drying-heated air removes residual moisture.

Rinsing of Instruments after Cleaning.

The cleaning cycle of a washer disinfector incorporates a rinsing stage with freshly distilled water and a drying cycle leaving instrument ready for inspection under a magnification light.

Instruments must be sterilised as soon as possible after cleaning to avoid air drying (which can result in corrosion and/or microbial growth).

Instruments must be inspected for any visible soiling such as blood or dental materials. It is important to check joints hinges and serrated surfaces which are difficult to clean. If there is any residual contamination the instrument must be rejected and undergo another cycle of the cleaning process.

Avoiding Instrument Damage

Most dental instruments are made of high-quality materials designed to minimise corrosion if reprocessed correctly. The corrosion resistance is based on their alloy composition and structure, which forms a protective layer on the surface. The ability of the instruments to resist corrosion depends on the quality and thickness of this layer. It is important to avoid damage to this layer during cleaning. Therefore, use of wire brushes to aid removal of debris will be avoided.

Inspection and Care of Instruments before Sterilising

All instruments that have been through a cleaning process must be inspected to ensure they are clean, functional and in good condition prior to sterilising. An illuminated magnifier is used to make it easier to see any remaining debris, contamination, or damage.

Instruments may become damaged during use or suffer from general wear and

tear over their life span. If devices are found to be faulty or damaged during inspection and function testing they will be taken out of use and either repaired or replaced.

Instruments for repair will be returned either to their manufacturer or to a reputable repair company. They must be decontaminated in accordance with local guidelines and labelled to identify they have been through the decontamination process.

Lubricants

Lubricants may be required both for dental hand pieces and to ensure jointed instruments are not stiff. A non-oil-based lubricant will be used to avoid it interfering with the sterilisation process. Care must be taken to ensure that separate canisters of lubricant are used should instruments require oiling at various stages of the process to ensure that cross contamination does not take place. The different canisters will be labelled so that it is clear which canister is used for unclean instruments and which is used for instruments that have through the washer disinfector process. If the manufacturer recommends oiling post sterilisation again a separate canister will be used and labelled accordingly.

Type N Autoclaves-Process

Sterilisation is the process to render an object free from micro-organisms, including bacterial spores. Dental instruments must be classed as sterilised at point of usage as opposed to sterile, as it is appreciated that the Dental Surgery is not a sterile environment.

Type N displacement autoclaves are used across the dental service. They are suitable for unwrapped, non-porous items that can withstand temperatures of 137◦C. Instruments processed in a type N machine must not be bagged prior to sterilisation.

Following inspection, items loaded into the bench top steam steriliser must be arranged as described below to ensure the removal of air and to allow steam penetration.

- Scissors and forceps must be left open.
- Instruments must not touch or overlap each other.
- Trays or baskets must be open mesh and not solid.
- Bowls must be placed on their sides to allow condensation to run out.
- Following sterilisation instruments are bagged and dated with the expiry date; this is no more than one year from the date of processing as outlined in HTM 0105.

Equipment Validation and Maintenance

Inspection, maintenance, and testing of decontamination equipment must be carried out by trained and competent persons. Records form the competent person/service engineer must be sent to the authorised person. The authorised person must confirm the report and send to the department for record keeping.

PRE-ACQUISITION QUESTIONNAIRE

Produced by NHS Purchasing and Supply Agency, Scottish Healthcare Supplies, Northern Ireland CSA Regional Supplies Service and Welsh Health Supplies in conjunction with the Association of British Healthcare Industries

Please include a separate form for each model

This form is intended to supply prospective purchasers with information about equipment being considered for purchase. It is intended principally for pre-purchase information on electrical medical, dental, ophthalmic and laboratory equipment. The form may also be used for other products, including non-electrical items, and to give information prior to equipment being supplied on loan, in which case not all the questions will be relevant. Please ensure all relevant questions are answered.

For issue and completion by purchaser: PPQ Master Reference:	
A unique reference (preferably ten characters maximum) must be given by the supplier: Supplier's Reference:	
Generic Device Type:	Equipment Model:
Country of Origin:	Manufacturer:
Supplier:	Telephone No:
Fax No:	e-mail:

CE MARKING

1. a) Does the product carry the CE marking? YES ☐ NO ☐
   b) If YES, to which EC Directive(s):
   - i) Active Implantable Medical Devices Directive (90/385/EEC) YES ☐
   - ii) Medical Devices Directive (93/42/EEC) YES ☐
     If YES, state classification of device (93/42/EEC Annex IX) ☐
   - iii) *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) YES ☐
     If YES, is the device: For self-testing? YES ☐ Covered by Annex II: List A? YES ☐ List B? YES ☐ NO ☐
     For ii) and iii) above, Identification No. of Notified Body, if applicable ☐
   - iv) EMC Directive (89/336/EEC or superseding directive)) YES ☐
   - v) Low Voltage Directive (73/23/EEC) YES ☐
   - vi) Other Directive(s) (please specify) ☐

2. a) Is the product a 'custom-made device' (93/42/EEC)? YES ☐ NO ☐
   b) Is the product intended for 'clinical investigation' (93/42/EEC) or 'performance evaluation' (98/79/EC)? YES ☐ NO ☐
   If YES to a) or b) above, does the device comply with the UK Medical Devices Regulations? YES ☐ NO ☐

MANAGEMENT SYSTEM STANDARDS

3. a) Is the manufacturer currently registered to any management system standards (e.g. ISO 9001, ISO 14001, ISO 13485)? YES ☐ NO ☐
   If YES, please state the standard(s) and certification body: ☐
   b) Is the supplier's service and repair organisation currently registered to any management system standards? YES ☐ NO ☐
   If YES, please state the standard(s) and certification body: ☐

SAFETY STANDARDS

4. For products not CE marked to 1 b) i), ii) or iii) above, with which safety standard(s) does the product comply?

Standard	*Test House*	*Certificate Number*	*Date*

SERVICE / SPARES / INSTALLATION

5. Is service/repair information available? YES ☐ NO ☐ If NOT f.o.c. please state current price ☐ Indicate contents below: ☐

(Please state YES, NO or N/A)

Full circuit diagrams	☐	Fault finding procedure	☐	Preventative maintenance	☐
Repair information	☐	Spare parts listing	☐	List of special tools/test equipment/etc	☐

If YES, please state whether also available on: Disk ☐ Website ☐ If Web, please state address ☐

6. a) In addition to the service/repair information/manual, will training be required before competent technical personnel can provide:
(Please state YES, NO or N/A)

First-line maintenance		Calibration	
Planned preventative maintenance		Repair	

b) Is the supplier able to provide this training for the purchaser's or a third party's technical personnel? YES NO
If YES, will this be free of charge? Or chargeable?
If NO, please indicate if details of an organisation that is able to provide this training are available on request? YES NO

Supplier's Reference:

c) Is the provision of service/repair information conditional upon completion of training? YES NO
d) In order to undertake maintenance/repair/calibration, is any special software/test equipment/tooling required? YES NO
If YES, please indicate that details of special software/test equipment/tooling are provided on a separate sheet: YES

7. a) Is the supplier able to provide an 'as required' repair/maintenance service in the UK? YES NO
b) Is the supplier able to provide a contract repair/maintenance service? YES NO
If YES, please confirm that details of repair/maintenance contracts are provided on a separate sheet. YES
c) i) If repairs are normally performed by the supplier on the purchaser's site, please state typical response time:
ii) If repairs are performed off-site, where will these be carried out?
Company: Location: Typical turnaround time:
iii) Is free of charge loan equipment normally available? YES NO

8. Please state if repair parts will be available to the purchaser's or a third party's suitably trained and equipped personnel: YES NO
If YES, is the supply of repair parts conditional upon acquisition of repair information? YES Or training? YES NO

9. Please indicate when this model was first placed on the market:

10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?
b) Is the product still in current production? YES NO If NO, indicate year of last manufacture:

11. Is installation necessary? YES NO
If YES, please confirm that details of all services required are provided on a separate sheet: YES

12. Will software upgrades be notified? N/A YES NO

IONISING RADIATION

13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation? YES NO

DECONTAMINATION / REPROCESSING

14. a) i) Will the item be reprocessed (cleaned, disinfected, sterilised)? YES NO If NO, go to Question 15.
ii) If YES, is the item intended to be: Non-sterile for single use Sterilised Disinfected Other
iii) Is there a recommended maximum number of uses? YES NO If YES, please state:
iv) Are decontamination/reprocessing instructions supplied? YES NO
v) Are instructions available for safe disposal? YES NO
b) i) Is manual cleaning the only cleaning method specified before further reprocessing? YES NO
ii) What is the maximum temperature that can be used for thermal disinfection? Temp:
iii) Are there any restrictions on detergent/disinfectant types? YES NO If YES, please state:
iv) Can the item withstand autoclaving at 137 °C for 3 mins? YES NO
v) Is the item compatible with other sterilization methods? YES NO If YES, please state:
vi) Does reprocessing require the use of specified equipment? YES NO
If YES, please state equipment type (e.g. containers, processors, etc) and, where appropriate, parameters of operation (e.g. temp, pressure, etc):

c) i) Are tools required to aid dismantling/reassembly, or are lubricants required? YES NO
ii) If YES, are they supplied with the device or available optionally? Supplied Optional Neither
d) Is decontamination/reprocessing training available? YES NO If YES will this be: Free of charge? Chargeable?
e) Are reprocessing instructions available on the Web? YES NO If YES, please state address:

WARRANTY

15. Please confirm that a copy of the warranty is provided on a separate sheet: YES ☐

DECLARATION

When reference is made to this form and its attachments within the process of obtaining the item, we agree that the purchaser will be entitled to rely upon the contents and subsequent non-compliance with the statements contained herein will entitle the purchaser to seek redress.

Name:	Position:
Company/Address:	Date:

DECONTAMINATION CONSIDERATIONS PRIOR TO THE PURCHASE OF MEDICAL EQUIPMENT.

This form is intended to supply prospective purchasers with decontamination information concerning equipment being considered for purchase.

Please ensure all relevant questions are answered.

1. Equipment

……

2. Company Name & Address

……

……

Can any part of the exterior or interior of the equipment be contaminated by blood, saliva, urine, or other bodily secretion? **YES / NO**

3.

If **'YES'** please specify

……

……

4. Does it require dismantling? **YES / NO**

If **'YES'** please specify

……..

……....

5. *Does the equipment require:* ***Cleaning [ ] Sterlising [ ] Disinfection [ ]***
(√ as appropriate)

6. **Equipment for Cleaning**: Please state method

……

7. **Equipment for Sterilisation**

Can the product be sterilised by returning to CSSD department?
YES / NO

If **'NO'** please specify how to be sterilised

……

……

8. Equipment for Disinfecting

Can the product be cleaned & disinfected by current chemical used for disinfection?

YES / NO

If '**NO**', what disinfectant is advised by the Company and at what dilution?

……

……

……

Are there any other specific problems in decontaminating this equipment?

……

……

Signed	Name:	Designation:	Date
Review by	Name:	Designation:	Date

A decontamination protocol MUST be written and available BEFORE the equipment is introduced into use. If there are any unresolved problems, please refer to the Trust Decontamination Lead.