STERILIZATION OF RE-USABLE MEDICAL DEVICES (DENTAL SERVICES) POLICY
POLICY NO. ICP8

<table>
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<th>Applies to:</th>
<th>Community Dental Service</th>
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<tr>
<td>Group for Approval</td>
<td>Infection Prevention and Control Group</td>
</tr>
<tr>
<td>Date of Approval</td>
<td>13 June 2013</td>
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<td>Committee for ratification</td>
<td>Quality and Governance Committee</td>
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<tr>
<td>Date Ratified</td>
<td>15 July 2013</td>
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<td>Review Date:</td>
<td>June 2016</td>
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<tr>
<td>Name of Lead Manager</td>
<td>Head of Infection Prevention &amp; Control Clinical Director Community Dental Services</td>
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UNLESS THIS VERSION HAS BEEN TAKEN DIRECTLY FROM TRUST WEB SITE THERE IS NO ASSURANCE THIS IS THE CORRECT VERSION
**CONTROL RECORD**

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<td>To ensure local decontamination processes are undertaken in line with national guidance and are fit for purpose</td>
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<tr>
<td>Author</td>
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<td>Equality Assessment Screening</td>
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**VERSION CONTROL RECORD**

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**Appendices**

| Appendix 1 | Monitoring Tool |
Sterilization of Re-Usable Medical Devices (Dental Services) Policy

1. INTRODUCTION

This policy covers the operational management of equipment used for cleaning and sterilization of dental equipment in line with Health Technical Memorandum 01-05: Decontamination in primary care dental practices.

Community Dental Service is the only service authorised to undertake local reprocessing (sterilization) of instruments within Wirral Community NHS Trust (WCNHST).

2. STATEMENT OF INTENT

There is a legal requirement on all NHS organisations to demonstrate compliance with The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance (Department of Health, 2010).

The aim of this policy is to ensure that equipment required to have completed a sterilization process is fit for purpose and equipment used for this process is suitable for the intended load, appropriately maintained and safely used to produce equipment in a sterilized state. The reprocessed dental instrument will be compliant with the Essential Requirements of the Medical Devices Regulations 2002.

This policy applies to all staff employed by the Trust working in the Community Dental Service. It does not replace HTM 01-05: Decontamination in primary care dental practices Health Technical Memorandum 01-05: Decontamination in primary care dental practices, and should be read in conjunction with the Trust Health and Safety policies and supporting IPC policies which are available on the Trust intranet site.

3. EQUALITY IMPACT ASSESSMENT

As part of its development, this policy and its impact on equality have been reviewed using the Policy Equality Impact Assessment Screening tool. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified.

4. DEFINITIONS

Validation: Means, by which an entire process is verified, tested and documented with the ability to be consistently reproducible.

Cavitations: rapid formation and collapse of minute bubbles in a liquid.

Endotoxin: a toxin contained within certain gram-negative bacteria which is only released when the bacterial cell wall is broken down or when it dies and disintegrates.
Ultrasonic: high frequency, high intensity sound waves.
Prion: an infectious pathogen that is composed primarily of protein.

5. DUTIES/RESPONSIBILITIES

5.1 Chief Executive

The Chief Executive has overall responsibility for decontamination within the Trust. The Trust has a responsibility for ensuring that it corporately meets its legal responsibilities in relation to decontamination. This responsibility is delegated to the Director of Infection Prevention and Control who is the Trust Decontamination Lead.

Trust Board

The Trust Board has a responsibility for ensuring that it corporately meets its legal duties in relation to decontamination. This responsibility is delegated to the Quality and Governance Committee via the Infection Prevention and Control Group.

Quality and Governance Committee

The primary function of the Quality and Governance Committee is to provide assurance to the Board of overall compliance with all statutory and regulatory obligations and will ensure the effective management of incidents, complaints, and subsequent dissemination of lessons learnt. The Quality and Governance Committee is responsible for ratifying Infection Prevention and Control policies.

Infection Prevention and Control Group

The Infection Prevention and Control Group are responsible for approving Trust Infection Prevention and Control policies and for monitoring incidents in relation to decontamination.

5.2 Decontamination Lead

It is the responsibility of the Decontamination Lead to oversee the development and implementation of decontamination guidance and policies for WCNHST Dental Service and to ensure that the Trust has safe effective systems in place to enable effective decontamination.

The Infection Prevention and Control Service

The IPCS are responsible for developing Trust wide policies. The IPCS are responsible for ensuring this policy is reviewed and amended at the review date or prior to this.

The Infection Prevention and Control Service (IPCS) are responsible for assuring the Trust board regarding activity in infection prevention and control within the Trust. Written reports are submitted four times per financial year.
Divisional Manager

The Divisional Manager will ensure that appropriate actions are taken for issues reported/escalated directly via the Infection Prevention and Control Group, Divisional Governance meetings/Service Leads and any other relevant Committee or Group.

5.3 Clinical Director Dental Service

It is the responsibility of the Clinical Director to ensure;

- Appropriate staff are aware of this policy,
- Staff are trained in the safe operation, testing and maintenance of decontamination equipment.
- Completion of decontamination records.
- Service Assurance Reports are submitted to the Infection Prevention and Control Group.

5.4 Employees

Employees who undertake decontamination are responsible for;

- Following policy and protocols for the safe reprocessing of dental instruments.
- Attending mandatory training programmes as set out in Service training matrices.

5.5 Head of Estates – (Designated Person)

It is the responsibility of the Designated Person to ensure the Trust Salaried Dental Services are provided with a contracted maintenance service for decontamination equipment. This will include

- **Authorising Engineer (Decontamination)** to provide guidance and advice on the implementation of the processes detailed in the HTM 01-05 and associated guidance

- **Authorised Person (Decontamination)** (A.P.) to provide advice on sterilizers and washer disinfectors to WCNHST Dental Services. To audit, review and witness documentation on validation annually. The annual report produced is to be presented to the Trust Infection Prevention and Control Group

- **Competent Person (Decontamination)** to be responsible for the servicing, testing and maintenance of Trust decontamination equipment

- **Competent Person (Pressure vessels)** who has legal responsibility for undertaking examinations of the sterilizer pressure systems in accordance with the written scheme of examination

- **Service Engineer(s)** appropriately trained and competent to undertake servicing and testing and validation of specific decontamination equipment used within PCT Health General Dental Practices
6 LEGAL OBLIGATIONS

- Health and Safety at Work Act 1974
- The Management of Health and Safety at Work Regulations 1999
- The Workplace (Safety, Health and Welfare) Regulations 1992
- The Provision and Use of Work Equipment Regulations 1998
- Pressure Systems Safety Regulations (PSSR) 2000
- Control of Substances Hazardous to Health Regulations 2004
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995
- Personal Protective Equipment at Work Regulations 1992
- Consumer Protection Act 1987
- Electromagnetic Compatibility Regulations 2006
- Medical Devices Regulations 2002

7 DECONTAMINATION FACILITIES

The Trust provides dental clinics at the following sites and is compliant with Best Practice Standards as set out in HTM 01-05.

- Devonshire Park Dental Centre
- Victoria Central Health Centre
- Leasowe Primary Care Centre

Accredited CSSD services are used by dental services provided at;

- Wirral University Teaching Hospital
- Clatterbridge Cancer Centre

8 NEW BUILDS/MAJOR REFURBISHMENTS

All new builds/major refurbishments must meet best practice standards as directed in HTM01-05 Decontamination in Primary Care Dental Services.

9 PRION DISEASE

There is currently no recognised process that can fully deactivate prion proteins.

There is a theoretical risk that low levels of prion contamination may be present on some instruments used for endodontic procedures when used on a carrier of prion disease but not exhibiting symptoms.

Instruments with the highest possible risk must be single use;

- Endodontic files – are single use items within the Trust
- Reamers – are not used within the Trust
- Matrix bands, saliva ejectors, aspirator tips and three-in-one tips – single use items within the Trust
10 CLEANING PROCESS

The effectiveness of the sterilizing process is dependant on the effectiveness of the cleaning process.

Washer disinfectors provide reliable, repeatable processes that can be validated and are the first choice for cleaning of dental instruments within the Trust.

Hand washing of dental instruments should only be undertaken in line with service protocol for manual cleaning when other mechanical methods are inappropriate, or unavailable e.g. failure of washer disinfector.

Instruments should be cleaned as soon as possible following use to prevent the absorption of proteins through drying. To decrease the risk of drying, spraying with specific foams or gels will help to maintain a moist environment.

10.1 Ultrasonic baths:

Ultrasonic cleaning is dependant upon cavitation which is produced by introducing ultrasonic sound waves into a liquid. The consequent agitation creates a highly penetrative cleaning system.

Ultrasonic baths may form part of an automated process or be a stand-alone.

The following may alter the efficiency of the system:

- Detergent/enzymatic concentration. (An over concentration of cleaning agent will reduce the ultrasonic activity. Only use detergent/enzymatics compatible with the ultrasonic bath used.
- Ultrasonic frequency
- Water temperature
- Exposure time
- The type of soiling

Validation, Maintenance and Testing:

Ultrasonic cleaners should be validated, maintained and serviced according to the manufacturer's instructions. Ultrasonic cleaners should be tested quarterly to ensure it is fully functional. Where manufacturers recommendations are not available ultrasonic cleaners should be maintained to the testing protocol outlined in HTM 01-05.

Daily maintenance/tests
- Drain machine at the end of the day
- Remove and clean any filters or strainers
- Visual inspection of all items for cleaning efficiency

Additional weekly maintenance/tests
- Check condition of door seal if present
• Undertake protein residue test

Health and Safety:
• Ensure the ultrasonic bath lid is in place before commencing process and is not removed until cycle is complete
• Never place hands into an active ultrasonic bath

10.2 Automated washer disinfectors:
• Ensure instruments are compatible for processing with washer disinfecter
• Do not overload instruments carriers or overlap instruments
• Open instrument hinges and joints fully

Inspection of cleaned instruments:
Instruments must be visually inspected following the cleaning process; task lighting and magnification must be available. This process must ensure there is no visual particulate contamination, salt deposits or marked discolouration indicating contamination.

Instruments identified as contaminated must be re-cleaned and inspected prior to sterilization.

Validation, Maintenance and Testing:
Washer disinfecters should be validated, maintained and serviced according to the manufacturer's instructions.

Daily maintenance/tests
• Remove and clean any filters or strainers
• Visual inspection of all items for cleaning efficiency

Additional weekly maintenance/tests
• Check condition of door seal
• Undertake protein residue test

11 BENCHTOP STEAM STERILIZERS

Steam sterilization has high lethality, it is rapid and non-toxic.

• Traditional (non vacuum - gravity displacement) Type N benchtop steam sterilizers are used within the Trust. These are intended to sterilize solid instruments (no lumens) that are not wrapped
• New sterilizers must not be used by the operator without evidence that the machine has been installed, commissioned and validated by the appointed contractor
• The sterilizer must only be used to process types and weights of loads specified by the manufacturer
• All sterilizers must have a current written scheme of examination undertaken by the appointed Competent Person. This is a requirement under the Pressure Systems Safety Regulations 2000 (PSSR)

**Maintenance of reservoirs and sterilizer chamber:**

It is possible for benchtop sterilizer loads to be contaminated by impurities in the water used to generate the steam to reduce the risks:

• Water used in the reservoir should be sterile water for irrigation
• Do not top up the reservoir, drain and replace if required
• Water in the reservoir must be drained at the end of the working day or session

The effectiveness of the process depends on direct contact between the steam and all surfaces of the load.

Prior to placing in the benchtop steam sterilizer items must be clean and dry. Contamination with residual tissue, body fluids, oil or other deposits:

• Will prevent contact between the steam and the surfaces of the load
• Might become fixed to the load items and may be difficult to subsequently remove
• Might contaminate the water and encourage bacterial growth

The chamber must not be overloaded as this may impair air removal. Retained air can prevent steam contact, sterilisation cannot be guaranteed.

**Management of sterilizer malfunction:**

• On no account should any safety feature be interfered with, circumvented or overridden
• Should the sterilizer fail the approved contractor should be contacted immediately and the error number displaced on the sterilizer display quoted
• Never attempt to open the door when a fault message appears, this may result in hot water being spilt and possible injury to the operator
• Instruments within a failed cycle cannot be considered processed. Instruments must be reprocessed in an alternative sterilizer or when the sterilizer is back in working order

**Installation, validation and periodic testing:**

Autoclaves should be validated, maintained and serviced according to the manufacturer’s instructions. Where manufacturers recommendations are not available washer-disinfectors should be maintained to the testing protocol outlined in HTM 01-05 Part 3.

Daily maintenance/tests
• Automatic control test (test run recording and checking temperature and pressure throughout the cycle, manually or by the data printer)
12 RECORDS

Permanent records must be held for each sterilizer and washer disinfector as evidence that it was/is functioning correctly and achieving sterilisation conditions and for annual audit purposes by the Authorising Engineer (Decontamination). Some of these records may be held by the appointed contractor. Records should be available throughout the life of the equipment and it is therefore advised that they should be retained for approximately eleven years. Documentation provides the only evidence of completed work.

Records required are:
- Specification
- Commissioning and validation tests/report
- Performance qualification details (Loading patterns and required parameter details)
- Routine monitoring of every sterilization and washer disinfector cycle
- Actions taken to correct a failed cycle, including details of management of the failed load
- Results of autoclave daily and weekly tests undertaken by the operator, quarterly and annual tests undertaken by the Test Person*
- Details of maintenance, repair or modifications
- Records of the inspection under the written scheme of examination (PSSR)
- Valid autoclave third party insurance certificate which covers the particular risks associated with pressurised equipment and steam.
- Evidence of operator training.

13 STORAGE OF INSTRUMENTS AFTER STERILIZATION

Instruments are considered sterilized not sterile at point of use when they are
- Placed in an instrument pouch following reprocessing
- Used directly following sterilization cycle

Instruments should be stored in a secure clean and dry environment in cleanable cupboards above floor level, away from direct sunlight and water.

Unpackaged instruments required for immediate use must be:
- Dried with a disposable non-linting cloth if wet following sterilization
- Stored on trays and covered to protect against dust or aerosol contamination
- Used within one session
- Unused instruments must be reprocessed before use in another session

Sterilized instruments processed in a non vacuum steam sterilizer stored for later use must be
- Stored in a clean, disinfected, dry airtight container or in sterilized lidded instrument trays in clean decontamination room. **Use within 1 week**
- Placed in single use sealed view instrument pouches (instruments must be dried thoroughly by the autoclave drying cycle before opening the door as microbiological contamination can occur through wet/damp packaging. If drying cycle not available a disposable non-linting cloth may be used). **Use**
within 12 months. Following this the instruments must be reprocessed and stored in new pouches

- All pouches must be labelled with date of sterilization and expiry date
- A stock rotation system must be used
- Expiry dates must be checked and documented on a regular basis

14 REPROCESSING OF DENTAL HANDPIECES

Handpieces must be cleaned and sterilized after each patient contact. The DAC Universal Handpiece Cleaner is used in all sites undertaking local decontamination within the Community Dental Service.

In the event of failure of the DAC Universal Handpiece Cleaner, handpieces must be manually cleaned and sterilized in a benchtop sterilizer. Manufacturers guidelines should be followed for lubrication, however non oil based lubricants need to be used. Separate canisters of lubricant are required for dirty and clean instruments.

15 USE OF LUBRICANTS

Lubricants must be used in line with the manufacturer’s instructions. Use and over use of lubricants will introduce contaminants into the sterilizer water system and chamber. It is essential to change the water daily in sterilizers which re-circulate water during successive cycles, to limit this contamination.

16 TRANSPORT OF INSTRUMENTS

Within the clinic:

There must be a safe procedure for the transport of used instruments from the treatment room/area to the decontamination room/area.

Containers should be

- Leakproof
- Easy to clean
- Rigid and robust and capable of reprocessing in a washer disinfector
- Capable of being closed securely with a well fitting lid
- After use - cleaned, disinfected and dried*

* Do not use bleach based products on the transport container as residues may damage instruments.

Externally i.e. school or home visits:

This is for instruments used for treatment or education by the person transporting them

- Separate containers should be used for clean and used instruments
- Containers for clean and used instruments should meet the requirements above
- Instruments should be stored securely in the vehicle – i.e. in the boot area
- Records must be kept of date and vehicle used
17 TRAINING

Decontamination training is a mandatory requirement for staff who undertake such procedures as identified on Service Training Matrices.

All core mandatory training is recorded centrally by the Quality and Governance service. Quarterly monitoring reports are prepared for the Learning and Development Group to monitor attendance rates. Full details of the processes in place for managing and monitoring attendance are set out in the Policy for Learning and Development GP46.
REFERENCES


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<th>Evidence</th>
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<td>Minutes &amp; Service Assurance reports 6 monthly HTM 01-05 audit</td>
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