POLICY FOR SINGLE USE MEDICAL DEVICES
INFECTION PREVENTION AND CONTROL POLICY NO. 6

<table>
<thead>
<tr>
<th>Applies to</th>
<th>Employees of Wirral Community NHS Trust</th>
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<tbody>
<tr>
<td>Group for Approval</td>
<td>Infection Prevention &amp; Control Group</td>
</tr>
<tr>
<td>Date of Approval</td>
<td>19 September 2012</td>
</tr>
<tr>
<td>Committee for ratification</td>
<td>Quality and Governance Committee</td>
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<tr>
<td>Date Ratified</td>
<td>2012</td>
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<tr>
<td>Review Date:</td>
<td>September 2015</td>
</tr>
<tr>
<td>Name of Lead Manager</td>
<td>Head of Infection Prevention &amp; Control</td>
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<td>Version</td>
<td>1</td>
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1. INTRODUCTION

The reprocessing and reuse of single-use medical devices is a long standing practice although the Medicines and Healthcare products Regulatory Agency (MHRA) advises against this. Users often justify the reprocessing of such devices on the basis of economic and environmental benefits.

To reuse a single-use device without considering the consequences could expose patients and staff to risks which outweigh the perceived benefits of using the devices. These perceived benefits are questionable as many of the processes required to ensure that the device is safe and fit for its intended purpose cannot be undertaken by the reprocessor (a person who undertakes the reprocessing of a medical device). MHRA 2011.

2. STATEMENT OF INTENT

It is the Policy of this Trust that medical devices identified by the manufacturer as single use will never be reprocessed within a clinic or community setting and used for another patient.

This policy outlines the Trust's responsibilities in relation to Single Use Medical Devices.

To comply 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) WCNHST will:

- draw to the attention of staff, hazards and risks associated with reprocessing and reusing single-use medical devices
- use medical devices safely and appropriately
- not reuse single use items

WCNHST staff must not reuse a single use medical device under any circumstances.

3. DEFINITIONS

Single-use – The expression ‘single-use’ means that the medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient

Cleaning – A process that physically removes contamination but does not necessarily destroy micro-organisms

Decontamination – A process which removes or destroys contamination and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Three
processes of decontamination are commonly used: cleaning, disinfection and sterilisation

**Disinfection** – A process used to reduce the number of viable microorganisms but which may not necessarily inactivate some bacterial agents, such as certain viruses and bacterial spores

**Endotoxin** – Is a toxin lipopolysaccharide, formed by the breakdown of the cell wall of Gram-negative bacteria. Bacterial endotoxins can be active even if the bacteria from which they are released are killed

**Intended purpose** – The use for which the device is intended according to the information supplied by the manufacturer on the labelling, in the instructions and/or promotional materials

**Legal entity** – An individual, institution or organisation that has its own existence for legal or tax purposes e.g. a corporation, partnership or trust

**Manufacturer** – The person with responsibility for the design, manufacture, packaging and labelling of a device before placing it on the market under its own name, this can be a company or an individual

**Medical device** – Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of:

- Control of conception
- Diagnosis, prevention, monitoring, treatment or alleviation of Disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- Investigation, replacement or modification of the anatomy or physiological process.

**Prions** – Infectious agents, smaller than viruses. Unlike other pathogens, prions contain no DNA or RNA. Their only known component is a protein with an abnormal conformation

**Professional user** – The trained and qualified person who operates a device for the benefit of the patient

**Reprocess** – To make good the device for reuse by any or a combination of the following processes:

- Cleaning
- Disinfection/decontamination
- Sterilization
- Refurbishment
- Repackaging
Note: the manufacturer of reusable devices should provide validated reprocessing instructions along with the device.

Reprocessor – A person who undertakes the reprocessing of a medical device

Re-sterilisation – The repeated application of a terminal process designed to remove or destroy all viable forms of micro-organisms, to an acceptable level of sterility

Reuse – Another episode of use, or repeated episodes of use, of a medical device, which has undergone some form of reprocessing between each episode

4. EQUALITY IMPACT ASSESSMENT

As part of its development, this policy and its impact on equality have been reviewed. 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.

5. DUTIES

Chief Executive

The Chief Executive has overall responsibility for Infection Prevention and Control within the Trust.

Trust Board

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

Director of Quality and Governance/Director of Infection Prevention and Control

It is the responsibility of the Director of Quality and Governance/Director of Infection Prevention and Control to oversee the development and implementation of infection prevention and control policies. It is also their responsibility to review compliance with Infection Prevention & Control audits and address issues of non-compliance.

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 is responsible for approving Trust Infection Prevention and Control policies. The group is also responsible for monitoring Service Assurance reports containing results of Service’s Annual Audit results and outcomes as part of unannounced inspection visits.

The Infection Prevention and Control Service

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.

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, following new developments with Single Use Medical Devices.

Divisional Managers/Service Leads

Divisional Managers or Service Leads are responsible for booking staff onto mandatory training via the Learning and Development team. Service Leads have overall responsibility for monitoring attendance at mandatory staff training in relation to infection control within their Service in accordance with the Trust training matrices and dealing with non-attendance in line with Trust policy. Attendance at Essential Learning and Core Clinical Training is centrally recorded by the Learning and Development section of the Quality and Governance Service. Written reports for Essential Learning are made available to Divisional Managers or Service Leads via the Learning and Development group.

Divisional Managers and Service Leads are responsible for monitoring and ensuring compliance with Infection Prevention & Control audits within their service areas and reporting areas of non-compliance to the Infection Prevention and Control Group.

Managers

Managers are responsible for booking places on mandatory training and ensuring that staff attend infection prevention and control training in line with Trust training matrices and where informed of non-attendance at mandatory training ensure appropriate action taken in line with the Trust Learning and Development policy.

Learning and Development Team

The Learning and Development Team are responsible for coordinating mandatory training and notifying Service Leads if staff fail to attend. Attendance at Essential Learning and Core Clinical Training is centrally recorded by the Learning and Development section of the Quality and Governance Service.
Employees

Employees are responsible for complying with the principles detailed within this policy. Employees are responsible for ensuring they attend mandatory training programmes as directed by their Line Manager. If staff are unable to attend a booked training programme, the training provider must be notified within 48 hours.

WCNHST staff must not reuse a single use medical device under any circumstances.

Employees must comply with Trust policies. Failure to comply with or act in accordance with Trust policies may result in disciplinary action.

6. PROCEDURE FOR SINGLE USE MEDICAL DEVICES

Definition of Single Use

The medical device is intended to be used on an individual patient during a single procedure and then discarded. The device is not intended to be reprocessed and used on another patient. The labelling identifies the device as disposable and not intended to be reprocessed and used again. Shown below is the symbol that identifies single use items. This will appear on packaging but might not be present on individual items for e.g. podiatry packs. If in doubt, further advice should be sought from the manufacturer.

Safety Issues

- Single use devices may not be designed to allow a thorough decontamination process.
- Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer’s specifications and performance may be compromised.
- Single use devices have not undergone extensive testing, validation and documentation to ensure the devices are safe to reuse. Infection is one of the greatest patient safety concerns associated with reuse. The risk of cross infection may increase due to the inability of the reprocessing system to completely remove viable micro-organisms. This may be due to design e.g. narrow lumens. Viable micro-organisms may be incompletely removed and be transferred to the next patient
- Some materials can absorb certain chemicals which can gradually leach from the material over time. For e.g. disinfectants may be absorbed by plastics and
leach out during use, resulting in chemical burns or a risk of sensitisation of the patient or user.

- Chemicals may cause corrosion or changes to the materials of the device. For e.g., plastics may soften, crack or become brittle.
- The material may experience stress during reuse and may fail, stretch or break.
- Inadequately cleaned equipment can carry bacterial endotoxins which remain after bacteria are killed.

The re-use of a single use device has implications under the Medical Devices Regulations. Anyone who reprocesses or re-uses a device CE–marked for use on a single occasion bears the responsibilities normally carried by the manufacturer for the safety and effectiveness of the instrument. This may then transfer legal liability for that item from the manufacturer to staff or the Trust, unless reprocessing methods have been validated to prove the safety of both the process, and the end product.

**Legal Implications, negligence and regulatory requirements**

The Trust acknowledges its responsibility to comply with the following legislation:

- Health and Safety at Work Act 1974
- Part 1 of the Consumer Protection Act 1987
- The General Product Safety Regulations 2005
- The Medical Devices Regulations 2002
- Care Quality Commission Essential Standards for Quality & Safety (2008)

**Single Patient Use**

Some items of equipment are identified as suitable for single patient use i.e. urethral catheters supplied within the community for intermittent use and continence treatment equipment. A medical device may be used for more than one episode on one patient only; the device may undergo some form of reprocessing between each use. Advice must be sought from the manufacturer or the Infection Prevention and Control Service on appropriate decontamination methods.

**Use of Medicines**

Medicines including topical medical products must be considered as single use items unless the label and/or the supporting manufacturers guidelines clearly state that they have been prepared as multi-dose items. A risk assessment must be carried out (in conjunction with Medicines Management) for each individual product.

**Prion Disease**

Prions are infective agents which contain no nuclear material. Prions multiply by changing normal cellular proteins into abnormal proteins which then accumulate in the central nervous system, where they can trigger neurological symptoms. Chemical and heat sterilisation are only partially effective at inactivating prion proteins. In order
to reduce the potential risk of transmission of prions during procedures in contact with nervous tissue, single use instruments are recommended. Although the risk of Variant Creutzfeld-Jacob Disease (vCJD) in dentistry is low, endodontic files and reamers should be treated as single use items.

Disposal of Single Use Equipment

Single use equipment must be disposed of following the Trust Management of Healthcare Waste Policy.

Patients Own Equipment, dressings and dressing packs

Patients who present to staff either in clinic or patients own home with their own equipment, dressings or dressing packs which have been opened must be advised that these cannot be used due to the possible risk of infection and possible compromise to patient safety. The equipment, dressings or dressing packs are to be returned to the patient as they are the patient’s property or can be disposed of by the staff member with the patient’s consent.

7. TRAINING/SUPPORT

Infection Prevention and Control training (including Single Use Medical Devices) is a mandatory requirement for both clinical and non clinical staff as detailed in the Trusts core mandatory 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. The process for managing persistent non-attendance within the organisation is set out in the Policy for Learning and Development GP46 section 8.2.

The Infection Prevention and Control Service can be contacted for further advice or support.

8. PROCESS FOR MONITORING EFFECTIVE IMPLEMENTATION

An annual programme of audit is completed by The Infection Prevention & Control Service of all clinical areas within the Trust. A number of planned unannounced visits take place and nominated areas or staff groups are visited by the Director of Quality & Governance/Director of Infection Prevention & Control and an Infection Prevention & Control Nurse.

The Infection Prevention & Control Group monitors compliance with these audits and visits. Divisional Managers/Service Leads are responsible for ensuring compliance within their individual services. This is a requirement of The Health and Social Care Act 2008 Code of practice on the prevention and control of infections and related guidance (Department of Health, 2010)
9. OTHER RELEVANT PROCEDURAL DOCUMENTS

This policy should be read in conjunction with relevant Organisational documents.

10. REFERENCES

Department of Health 2009 Decontamination
Health Technical Memorandum 01-05: Decontamination in primary care dental practices.


MHRA DB 2006(04) v.2.0 December 2011 Single-use Medical Devices: Implications and Consequences of Reuse.
### Appendix 1

#### Process for Monitoring Compliance with Single Use Medical Devices policy

<table>
<thead>
<tr>
<th>Minimum requirement to be monitored</th>
<th>Process for monitoring (e.g. audit)</th>
<th>Responsible individual / group / committee</th>
<th>Frequency of monitoring</th>
<th>Evidence</th>
<th>Responsible individual for development of action plan</th>
<th>Responsible committee for monitoring of action plan and Implementation</th>
</tr>
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<tbody>
<tr>
<td>Duties</td>
<td>Audit</td>
<td>Infection Prevention &amp; Control Group.</td>
<td>Quarterly</td>
<td>Audit Report. Returned action Plan</td>
<td>Divisional Managers/ Service Leads</td>
<td>Quality &amp; Governance Committee</td>
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<tr>
<td></td>
<td>Unannounced visit</td>
<td></td>
<td>6 times per year</td>
<td>Unannounced Visit Outcome Plan</td>
<td></td>
<td></td>
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<tr>
<td>Staff Training</td>
<td>Attendance at Mandatory training</td>
<td>Learning &amp; Development Group</td>
<td>Minimum of twice per year</td>
<td>Minutes/action plans of Learning &amp; Development Group</td>
<td>Divisional Managers/ Service Leads</td>
<td>Education &amp; Workforce Committee</td>
</tr>
<tr>
<td>Process for monitoring incidents</td>
<td>Datix Report</td>
<td>Head of Infection Prevention &amp; Control</td>
<td>Minimum four times per year</td>
<td>Minutes &amp; papers of IPCG</td>
<td>Divisional Managers/ Service Leads</td>
<td>Quality &amp; Governance Committee</td>
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Single-use Medical Devices

How do I know if a device is for single-use?

It will have this symbol on the packaging or the device:

Why shouldn't they be reused?

The MHRA is aware of serious incidents relating to reuse of single-use devices.

Reuse can be unsafe because of risk of:
- cross-infection – inability to clean and decontaminate due to design.
- endotoxin reaction – excessive bacterial breakdown products, which cannot be adequately removed by cleaning.
- patient injury – device failure from reprocessing or reuse because of fatigue, material alteration and embrittlement.
- chemical burns or sensitisation – residues from chemical decontamination agents on materials that can absorb/adsorb chemicals.

Also, if you reuse a single-use device you may be legally liable for the safe performance of the device.

What does single-use mean?

Do not reuse. A single-use device is used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

Can I sterilise a single-use device?

A few single-use devices are marketed as non-sterile. These may require processing, in line with the manufacturer’s instructions, to make them sterile and ready for use. You must not resterilise them.

Is single-patient use the same as single-use?

No. Single-patient use means the medical device may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use.