POLICY FOR SINGLE-USE, SINGLE PATIENT USE AND LIMITED USE MEDICAL DEVICES

Amendments

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<tr>
<th>Date</th>
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<th>Approved by</th>
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<tr>
<td>August 2009</td>
<td></td>
<td>Reviewed Changes made to layout to comply with ‘Policy Writing and Ratification’ policy</td>
<td>Medical Director (Chairman’s Action)</td>
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<tr>
<td>August 2012</td>
<td></td>
<td>Expiry of review date and review of MHRA DB 2006(04)v2.0 Dec 2011</td>
<td>Decontamination Group</td>
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Compiled by: Paul Cooper, Head of Estates & Facilities Infrastructure
Approved by: Decontamination Group
Ratified by: Clinical Governance Committee
Date: April 2007
Review Date: October 2012
Review due: August 2015
Target Audience: All Clinical Staff
Contact Name for Comments: Paul Cooper, Head of Estates & Facilities Infrastructure

Impact assessment carried out by: Paul Cooper, Head of Estates & Facilities Infrastructure
## POLICY FOR SINGLE USE, SINGLE PATIENT USE AND LIMITED USE MEDICAL DEVICES

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POLICY FOR SINGLE USE, SINGLE PATIENT USE AND LIMITED USE MEDICAL DEVICES

1. INTRODUCTION
The reprocessing and reuse of single-use medical devices is a longstanding practice, although the MHRA advises against this. Users often justify the reprocessing of such devices on the basis of economic and environmental benefits. 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). Many single-use devices are also reused without adequate evaluation of the increased risks to patients.

This policy is based on current recommendations made by the Medical Devices Agency (MDA) (now known as the Medicine and Healthcare Product Regulatory Agency MHRA)) which clearly states that "A device designated as single use must not be re-used" (MHRA DB 2006 (04) v2.0 December 2011)

It has also been formulated in order to meet Department of Health guidelines, which state ‘Never re-use medical devices designated for single-use’ (NHS Executive 1999).

2. AIM
The aim of this policy is to set out the legal issues and implications of improper use associated with medical devices that have been designated as Single-Use, Single Patient Use and Limited Use Medical Devices Items.

3. DEFINITIONS
For the purpose of this policy “singe use” is used as a generic term and refers to single use, single patient use and limited use medical devices

3.1 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.

3.2 SINGLE-USE DEVICE
A medical device intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be re-processed and used on another patient.

The expression ‘single-use’ on the packaging of medical devices means that the manufacturer:
- Intends the device to be used once and then discarded
- Considers the device is not suitable for use on more than one occasion
- Has evidence to confirm that re-use would be unsafe
The above symbol is used on medical device packaging indicating ‘Do Not Re-Use’ and may replace any wording.

Principles of ‘Single-Use’ Devices

1. Devices designated for ‘single-use’ must not be re-used.

2. The re-use of ‘single-use’ medical devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.

3. Re-processing a ‘single-use’ device may alter its characteristics so that it may no longer comply with the original manufacturer’s specifications and therefore the performance may be compromised.

4. The re-use of ‘single-use’ devices has legal implications.

3.3 SINGLE PATIENT USE
A medical device can be re-used, if re-processed in accordance with manufacture’s guidance and is used on the same patient only. The duration of use is dependent upon undertaking a risk assessment of individual risk factors, and in line with manufacturer’s instructions.

3.4 LIMITED USE
A medical device that is intended only for a specified number of uses, the device can be re-processed in accordance with manufactures guidance. The number of times each individual item can be, and is, reprocessed is documented and appropriate records of re-use are maintained. Controls and monitoring arrangements are to be in place to ensure that the agreed number of reprocessing episodes is not exceeded.

4. LEGAL IMPLICATIONS, NEGLIGENCE AND REGULATORY REQUIREMENTS
User organisations, professional users and reprocessors who prepare single-use devices for further episodes of use, may be transferring legal liability for the safe performance of the product from the manufacturer to themselves, or the organisation that employs them.

If a reprocessed device is supplied to another legal entity and the device is not fit for its intended purpose, the reprocessor and professional user may be committing an offence or contravening national guidance under one or more of the following:
Health and Safety at Work Act 1974 [2]
Such activities may contravene the provisions relating to ‘general duties’ and expose patients or staff to risk.

There may be exposure to civil liability, with payment of damages for any injury caused to another person by the device, either on the basis of negligence or under the strict liability provisions of Part I of the Consumer Protection Act 1987, if the device is found to be defective (i.e. does not provide the expected level of safety).

The General Product Safety Regulations 2005 [4] The General Product Safety Regulations apply when the device is intended for consumers or likely to be used by the consumer. They apply to the:

(a) producer – a manufacturer or importer. This includes a person who reconditions a product but only if he is not subject to the Medical Devices Regulations. It also includes any professionals in the supply chain whose activities may affect the safety of the device

(b) distributor – professionals in the supply chain whose activities do not affect the safety properties of the device. A producer is also required to provide consumers with relevant information to enable them to assess any such device for placing on the market.

The Medical Devices Regulations 2002 [1] Medical devices manufactured and placed on to the market within the United Kingdom (UK) and throughout the European Union (EU) are subject to specific regulation. These require that medical devices now placed on the market carry a CE marking. This denotes compliance with a number of essential requirements covering the safety and performance of the medical device.

Standards for Better Health [5] The Department of Health published Standards for Better Health (SfBH) in July 2004 and these were updated in 2006. All NHS organisations are required to take the SfBH into account when developing, providing and commissioning healthcare. The Care Quality Commission will use the standards as a key component of their assessments.

Part b of core standard C4 (Safe use of medical devices) is particularly relevant to medical devices and is ‘all risks associated with the acquisition and use of medical devices are minimised’.

5 TRUST POSITION
The reprocessing and reuse of single-use medical devices is a long standing practice, in some organisations, although the MHRA advises against this.

At Ashford & St Peters Hospitals NHS Foundation Trust. Medical devices designated as ‘single-use’ must not be re-used under any circumstances.
6 RESPONSIBILITIES
6.1 MANAGERS AND SENIOR STAFF
Managers and Senior Staff must ensure that medical devices designated as ‘single-use’ are not re-used under any circumstances and Medical Devices marked Single Patient Use and Limited Use are used according to the manufacturer’s guidelines.

It is the responsibility of all managers to ensure that all their staff receive appropriate training and understand the importance of correct use of Single Use, Single Patient Use and Limited Use equipment and the implications of re-using single use equipment.

6.2 ALL STAFF
It is the responsibility of all staff to ensure the correct use of Single Use, Single Patient Use and Limited Use equipment and that any problems identified are reported to their line manager.

6.3 STERILE SERVICES DEPARTMENT (SSD)
If a single-use device is sent for decontamination it is the responsibility of all SSD staff to quarantine the device and notify the SSD Manager or deputy who will:

- Dispose of the item appropriately
- Contact the department / area manager who sent the item for processing
- Record the above actions

The SSD will maintain accurate records of the number of times a ‘limited use device’ has been processed through the department ensuring that the manufacturers recommendations are not exceeded. The department / area manager will send “limited use devices” to SSD for decontamination, but they should also track the number of uses so they plan in advance for the replacement.

7 DISSEMINATION AND IMPLEMENTATION
This policy was reviewed by the Trust Decontamination Lead with the support of Infection Control, SSD manager, Health and Safety Advisor and in consultation with the Decontamination Group. It is ratified by the Clinical Governance Committee. The policy is available on the Trust web site.

8 PROCESS FOR COMPLIANCE WITH THE EFFECTIVENESS OF POLICIES
The purchase and use of single use items will be monitored by the Procurement Department, the Sterile Services Department, as well as all staff who have the responsibility to ensure compliance with this policy.
Where monitoring has identified deficiencies, recommendations and action plans will be developed and changes implemented accordingly.

9 IMPACT ASSESSMENT
Ashford & St Peters Hospitals NHS Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This policy does not discriminate against individuals or groups on any grounds. See Appendix A for the completed impact assessment tool.
10 ARCHIVING ARRANGEMENTS
This is a Trust-wide document and archiving arrangements are managed by Quality Department who can be contacted to request master/archived copies.

11 REFERENCES
Updated in-line with Medicines and Healthcare products Regulatory Agency (20011) Single Use Medical Devices: Implications and Consequences of Re-use DB2006(04)v2.0
APPENDIX A

EQUALITY IMPACT ASSESSMENT TOOL

POLICY FOR SINGLE-USE, SINGLE PATIENT USE AND LIMITED USE MEDICAL DEVICES

Name: Jacky Bush
To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

<table>
<thead>
<tr>
<th>1. Does the policy/guidance affect one group less or more favourably than another on the basis of:</th>
<th>Yes/No</th>
<th>Comments</th>
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<tr>
<td>Race and Ethnic origin (include gypsies and travellers) (consider communication, access to information on services and employment, and ease of access to services and employment)</td>
<td>No</td>
<td>For each category describe how you have involved stakeholders including service users and employees</td>
</tr>
<tr>
<td>Disability (consider communication issues, access to employment and services, whether individual care needs are being met and whether the policy promotes the involvement of disabled people)</td>
<td>No</td>
<td></td>
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<tr>
<td>Gender (consider care needs and employment issues, identify and remove or justify terms which are gender specific)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Culture (consider dietary requirements and individual care needs)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Religion or belief (include dress, individual care needs and spiritual needs for consideration)</td>
<td>No</td>
<td></td>
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<tr>
<td>Sexual orientation including lesbian, gay and bisexual people (consider whether the policy/service promotes a culture of openness and takes account of individual needs)</td>
<td>No</td>
<td></td>
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<tr>
<td>Age (consider any barriers to accessing services or employment, identify and remove or justify terms which could be ageist)</td>
<td>No</td>
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2. Is there any evidence that some groups are affected differently? 

No

3. If you have identified potential discrimination, for example, less than equal access, are any exceptions valid, legal and/or justifiable, for example a genuine occupational qualification? 

No

4. Is the impact of the policy/guidance likely to be negative? 

No
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<td>5.</td>
<td>If so can the impact be avoided?</td>
<td>N/A</td>
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<tr>
<td>6.</td>
<td>What alternatives are there to achieving the policy/guidance without the impact?</td>
<td>N/A</td>
</tr>
<tr>
<td>7.</td>
<td>Can we reduce the impact by taking different action?</td>
<td>N/A</td>
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**APPENDIX B**
Refer to MHRA Single-use Medical Devices leaflet.