

Device Bulletin

Single-use Medical Devices: Implications and Consequences of Reuse

DB2006(04) v2.0
December 2011
website only

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1 Executive summary

This is a revised version of the edition published in 2006.

To reuse a single-use device without considering the consequences identified in this document could expose patients and staff to risks which outweigh the perceived benefits of using the devices.

Key points:

- A device designated as 'single-use' must not be reused. It should only be 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.
- The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of single-use devices has legal implications:
 - > anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness;
 - > anyone who reprocesses a single-use device and passes it to a separate legal entity for use, has the same legal obligations under the Medical Devices Regulations [1] as the original manufacturer of the device.
- Check the packaging or device for the symbol below, which means do not reuse / use only once / single use.



This document is intended for:

- chief executives and managers of organisations where medical devices are used
- all professionals who use medical devices
- all providers of medical devices
- all staff who reprocess medical devices.

2 Introduction

The reprocessing and reuse of single-use medical devices is a long-standing 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 publication draws attention to the hazards and risks associated with reprocessing and reusing single-use medical devices. It covers the legal issues and regulatory requirements of such actions. It also considers the implications of damage to the materials or construction of the device and inadequate decontamination procedures.

3 Legal implications, negligence and regulatory requirements

User organisations, professional users and reproducers 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.

Part 1 of the Consumer Protection Act 1987 [3]

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'.

4 Safety issues

Reprocessing single-use devices may compromise their intended function.

Single-use devices may not be designed to allow thorough decontamination and (if applicable) resterilization processes.

Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer's specifications and, therefore, the performance may be compromised.

Single-use devices have not undergone extensive testing, validation and documentation to ensure the devices are safe to reuse.

4.1 Device design

A medical device made for reuse must work as well as it did on its first use every time that it has been reprocessed. The manufacturer will validate the device for reuse and provide adequate reprocessing instructions when the device is placed on the market.

A single-use device may be made in such a way that any reprocessing may damage or alter it to the extent of making it unsafe to reuse. If the device has been designed for single-use, the manufacturer need not undertake any reprocessing validation studies and is therefore not required to provide such information.

4.2 Identified problems involving the reuse of single-use devices

Most problems caused by inappropriate reuse of a single-use device fall into one or more of the following categories.

Potential for cross-infection

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 and the type of material used e.g. heat sensitive materials. Viable micro-organisms may be incompletely removed and be transferred to the next patient.

Example 1

A single-use bladder pressure transducer cover was not changed between patients, resulting in cross-infection due to *Pseudomonas aeruginosa*. One patient developed septicaemia and died of a sub-arachnoid haemorrhage.

Inability to clean and decontaminate

A satisfactory cleaning process for devices must be able to access all parts of the device to allow complete decontamination and at the end of that process the cleaning agents must also be able to be completely removed. This process should be validated, to establish that it will consistently provide results complying with its predetermined specifications. Examples of features of a device that make cleaning difficult are: acute angles, coils, long or narrow lumens, specialist surface coatings etc.

Residues from chemical decontamination agents

Some materials used in device manufacture can absorb or adsorb certain chemicals, which can then gradually leach from the material over time. For example, 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.

Material alteration

Exposure to chemical agents, such as cleaning agents and chemical sterilants, may cause corrosion and/or changes in the materials of the device. Exposure to elevated temperatures or pressure during the sterilization process may also alter the properties or cause degradation of the device material. For example, plastics may soften, crack or become brittle.

Mechanical failure

Some devices may experience stress during each cycle of reuse, leading to fatigue-induced failure and fracturing e.g. single-use drill burrs, saw blades, craniotomy blades.

Example 2

A lithotripter stone retrieval basket, which was a single-use device, had been reprocessed and appeared to be satisfactory for use. During the procedure, the cable was tightened and snapped, resulting in the basket remaining in the patient. Further surgery was required to retrieve it.

Reactions to endotoxins

Endotoxins are Gram-negative bacterial breakdown products and can be a significant problem if the device has a heavy bacterial load after use, which cannot be adequately removed by cleaning. The sterilization process will not inactivate the toxins, even when cleaning and sterilization is effective in killing the bacteria.

4.3 Prion diseases

Prions, the abnormal proteins associated with prion diseases (e.g. Creutzfeldt-Jacob disease [CJD] and variant Creutzfeldt-Jacob disease [vCJD]) are very resistant to all conventional methods of decontamination.

In order to reduce the risk of transmission of abnormal prion proteins during surgical procedures, the Department of Health issued advice describing the present state of knowledge of the risks of transmission of vCJD from one patient to another. Health Service Circular 1999/178, vCJD: Minimising the Risk of Transmission [6], states that 'devices designated for single episodes of use must not be reused under any circumstances whatsoever.'

In addition, the Advisory Committee on Dangerous Pathogens (ACDP) TSE Risk Management Subgroup published guidelines in 2003 – 'Transmissible spongiform encephalopathy agents: safe working and the prevention of infection' [7]. It has been updated and many annexes added since 2003 as more scientific information has become available.

5 Glossary

The following terms have been defined for the purpose of this bulletin:

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, sterilization.

Disinfection – A process used to reduce the number of viable micro-organisms 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.

Placing on the market – The first making available in return for payment or free of charge of a device, (other than a device intended for clinical investigation) with a view to distribution and/or use in the market, regardless of whether it is new or refurbished.

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.

Prion diseases – Fatal, infectious, neurodegenerative disorders with no known immunisation or treatment.

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

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.

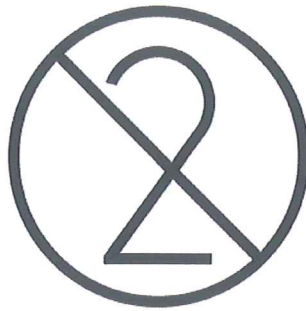
Reprocessor – A person who undertakes the reprocessing of a medical device.

Resterilization – 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.

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.

The symbol below is used on medical device packaging indicating 'do not reuse' and may replace any wording.



Some single-use devices are marketed as non-sterile which require processing to make them sterile and ready for use. The manufacturer of the device will include appropriate processing instructions to make it ready for use. (Symbol reproduced from BS EN 980:2003 'Graphical symbols for use in the labelling of medical devices', with permission from: BSI, 389 Chiswick High Rd, London W4 4AL. E-mail cservices@bsi-global.com, tel: 020 8996 9001).

Sterilization – A process used to make an object free from all viable micro-organisms including viruses and bacterial spores.

Validation – Documented procedure for obtaining and interpreting the results required to establish that a process will consistently yield a product complying with predetermined specifications.

User organisation – a device owner who makes use of the device e.g. a hospital trust.

6 References

- 1 The Medical Devices Regulations 2002. Statutory Instrument 2002 No. 618. HMSO 2002. ISBN 0110423178.
www.opsi.gov.uk
- 2 Health and Safety at Work etc. Act 1974. London: HMSO 1974.
<http://www.legislation.gov.uk/ukpga/1974/37/contents>
- 3 Consumer Protection Act 1987. HMSO 1987.
<http://www.legislation.gov.uk/ukpga/1987/43/contents>
- 4 The General Product Safety Regulations 2005. Statutory Instrument 2005 No. 1803. TSO 2005. ISBN 0110730542. www.opsi.gov.uk
- 5 Department of Health. Standards for Better Health, July 2004.
www.dh.gov.uk
- 6 Department of Health. Health Service Circular 1999/178, variant Creutzfeldt-Jakob Disease (vCJD): Minimising the Risk of Transmission.
http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4004969
- 7 ACDP TSE Risk Management Subgroup guidelines 'Transmissible spongiform encephalopathy agents: safe working and the prevention of infection' 2003
<http://www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm>

Further information:

Device Bulletin DB 2002(05) Decontamination of endoscopes.
www.mhra.gov.uk

BSI. BS EN 980:2003 Graphical symbols for use in the labelling of medical devices. www.bsonline.bsi-global.com

Note: websites last accessed December 2011.

Appendix

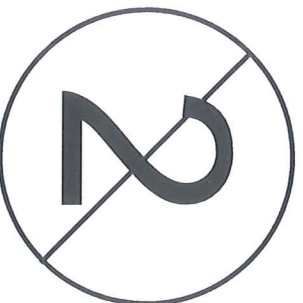
The next page shows a copy of a leaflet we have produced to clarify the meaning of the term 'single-use' and the symbol that is used to represent it.

Single-use Medical Devices

MHRA

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

It will have this symbol on the packaging or 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.

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.

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.

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.

Technical enquiries

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ISBN 978 1 90 073175 4