

REVIEW
DEVICES
BULLETIN

*Single-use
Medical Devices:
Implications and
Consequences
of Reuse*

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1. SUMMARY

This bulletin replaces the earlier bulletin *The Reuse of Medical Devices Supplied for Single-use Only* originally published in 1995 (DB 9501).

It has been rewritten to reflect:

- the implementation of the European Council – Medical Devices Directive (MDD) 93/42/EEC into United Kingdom law as the Medical Devices Regulations (MDR) June 1998;
- Health Service Circular HSC 1999/179¹ – Controls Assurance in Infection Control: Decontamination of Medical Devices;
- comments received from users on the first edition of this document.

Key points are:

- 1. Devices designated for ‘single-use’ must not be reused under any circumstances.**
- 2. The reuse of ‘single-use’ devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.**
- 3. The reuse of ‘single-use’ devices has legal implications.**
 - (a) 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.**
 - (b) 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 as the original manufacturer of the device.**

¹ The context of this Health Service Circular (HSC) is outlined in Appendix 1.

2. INTRODUCTION

The reprocessing and reuse of single-use medical devices is a long-standing practice, although the MDA 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. Many single-use devices are also reused without adequate evaluation of the increased risks to patients.

2.1 Who this document is 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.

2.2 Scope

This bulletin 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

3.1 Summary

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 under one or more of the following acts.

3.2 Health and Safety at Work Act 1974

Such activities may contravene the provisions relating to ‘general duties’ and expose patients or staff to risk.

3.3 Part 1 of the Consumer Protection Act 1987

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).

3.4 The General Product Safety Regulations 1994

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.

3.5 The Medical Devices Regulations 1994

Medical devices manufactured and put 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 (with the exception of *in vitro* diagnostic devices (IVD) and active implantable medical devices) placed on the market after June 13 1998 carry a CE marking. This denotes compliance with a number of essential requirements covering the safety and performance of the medical device.

4. TECHNICAL ISSUES

4.1 Summary

Reprocessing single-use devices may affect the capabilities and/or the materials from which the device is made.

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

4.2 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 design of the device dictates that it is for single-use, the manufacturer need not undertake any reprocessing validation studies and is therefore not required to provide such information.

4.3 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.

- **Inadequate cleaning and decontamination** – The cleaning process must access all parts of the device to enable complete decontamination and at the end of that process the cleaning agents must also be completely removed. This process should be validated, to establish that it will consistently provide results complying with its predetermined specifications. Features of the device, which make access difficult, are for example: acute angles, coils, long or narrow lumens, specialist surface coatings etc.
- **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 elevation in temperature or pressure during repeated sterilization processes may also alter the properties or cause degradation of the device material, e.g. plastics may soften, crack, become brittle etc.
- **Mechanical failure** – Some devices, if repeatedly reprocessed, 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 etc.

- **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. These micro-organisms may then go undetected and be transferred to the next patient.
- **Reactions to endotoxins** – Endotoxins are Gram-negative bacterial cell breakdown products which can be a significant problem if the device has a heavy bacterial load after use. The sterilization process will not inactivate the toxins, even when cleaning and sterilization is effective in killing the bacteria.
- **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 like glutaraldehyde may be absorbed by plastics and leach out during use, resulting in chemical burns or a risk of sensitisation of the patient or user.

Reprocessing a medical device designed or designated as single-use requires the process and the device to undergo extensive testing, validation and documentation to ensure the device is safe to reuse. There are few healthcare establishments equipped to carry out these procedures and therefore the use of a reprocessed single-use device is likely to be associated with significant risk.

5. PRION DISEASES

5.1 Summary

The abnormal proteins associated with prion diseases are very resistant to all conventional methods of decontamination.

5.2 Prions

Prions are infectious agents, smaller than viruses and unlike other pathogens, contain no DNA or RNA. Their only known component is an abnormally conformed protein. Prions replicate by transforming normal cellular prion proteins into abnormal isoform proteins. These abnormal prion proteins then accumulate in the central nervous system where they can trigger neurological symptoms. Prions may have inherited as well as acquired disease connections, commonly referred to as prion diseases.

5.3 Prion diseases

Prion diseases are fatal, infectious, neurodegenerative disorders with no known immunisation or treatment. Natural transmission of human prion diseases is not well understood because it is difficult to locate the source of transmission after a long incubation period. Currently there are four known human prion diseases:

- Kuru;
- Gerstmann-Straussler-Scheinker syndrome (GSS);
- Fatal Familial Insomnia (FFI);
- Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease (vCJD).

5.4 Inactivation of prions on medical devices

Most chemical and physical means of cleaning, disinfection and sterilization of medical devices are only partially effective at inactivating prion proteins.

- **Chemical means** – Detergents have almost no effect when used in concentrations that are safe in healthcare settings. Exposure to ethylene oxide for four hours only reduces the infectious nature of the prions by less than 10%. Immersion in glutaraldehyde for three weeks is only partially effective and both hydrogen peroxide and peracetic acid are ineffective. Research has indicated that sodium hypochlorite and sodium hydroxide are the most effective chemicals for reducing the infectivity of prions. Unfortunately sodium hypochlorite is extremely corrosive to most metals and fabrics and the active ingredient (chlorine) is reduced within one hour of application, making it difficult to control the efficacy of such solutions.
- **Physical means** – Abnormal prion proteins are very resistant to the common physical methods of decontamination.

In order to reduce the risk of transmission of 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, variant Creutzfeldt-Jakob Disease (vCJD): Minimising the Risk of Transmission, states that 'devices designated for single episodes of use must not be reused under any circumstances whatsoever.' Research on the most effective method of inactivating the protein is still ongoing and will be made available once complete.

6. CONCLUSIONS

To reuse a single-use device without considering the requirements and consequences identified within this document could expose the patient and reprocessor to risks which outweigh the perceived benefits of using such devices.

In particular:

- **Reprocessing 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.**
- **Reprocessing a medical device designed or designated as single-use requires extensive testing, validation and documentation. There are few user organisations equipped to deal adequately with these requirements.**
- **If a manufacturer has not declared the device as being suitable for reuse, it is then the responsibility of the user (in its widest term) to take all necessary steps to demonstrate that their actions are consistent with their duties of care to the patient and to staff.**
- **User organisations, professional users and reproprocessors who disregard this information and prepare single-use devices for further episodes of use without due precautions, may be transferring legal liability for the safe performance of the product from the manufacturer to themselves, or the organisation that employs them.**

APPENDIX 1. CONTROLS ASSURANCE

Summary

Guidelines for Implementing Controls Assurance in the NHS through the Clinical Governance Process have recently been introduced in the NHS.

Part of this framework includes a number of standards, one of which is *Infection Control – Controls Assurance Standard*.

Through this framework was introduced HSC 1999/179 – *Controls Assurance in Infection Control: Decontamination of Medical Devices*.

Controls assurance framework

The Controls Assurance project is designed to help NHS organisations achieve continuous and sustained improvement in their performance through effective risk management and internal control.

A series of standards have been recently introduced to promote a framework for managing the risks. These standards cover significant organisational risk areas and summarise relevant existing legislation, policies and guidance. One of these standards requires hospitals to assess their progress in managing hospital-acquired infection against national standards of good practice.

Within the Infection Control – Controls Assurance Standard, criterion 6 states: **‘Written policies, procedures and guidance for the prevention and control of infection are implemented and reflect relevant legislation and published professional guidance’**. A number of key policies are required to be in place, one of these is for single-use and single patient use devices and other healthcare products.

As part of the Controls Assurance process the Department of Health issued HSC 1999/179. Action (iv) of this document requires that relevant staff **‘Never reuse medical devices designated for single-use.’**

APPENDIX 2. GLOSSARY

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

Clinical governance – A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Controls assurance – A process designed to provide evidence that the NHS bodies are doing their reasonable best to manage themselves so as to meet their objectives and protect patients, staff, the public and other stakeholders against risks of all kinds.

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:

- (a) **Cleaning** – A process that physically removes contamination but does not necessarily destroy micro-organisms.
- (b) **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.
- (c) **Sterilization** – A process used to make an object free from all viable micro-organisms including viruses and bacterial spores.

Endotoxin – Is a toxic 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.

End user – The patient or client on whom the device is used.

Episode of use – May consist of several actions; only when the device is prepared (e.g. decontaminated) in readiness for a further session is it considered to be reprocessed for reuse.

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.

Manufacturer – The person with responsibility for the design, manufacture, packaging and labelling of a device before placing it on the market under his/her 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 handicap.
- 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.

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.

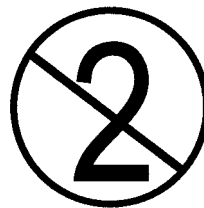
Reuse – Another episode of use, or repeated episodes of use, of a medical device, which has undergone some form of reprocessing between each episode.

Single-use – The 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 labelling identifies the device as disposable and not intended to be reprocessed and used again.

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.

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 reuse would be unsafe.



The above symbol is used on medical device packaging indicating ‘Do Not Reuse’ and may replace any wording. See Appendix 3 for other associated symbols used on medical devices and their packaging.

Single patient use – More than one episode of use of a medical device on **one patient only**, the device may undergo some form of reprocessing between each use.

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

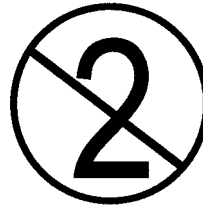
User organisation – a device owner who makes use of the device e.g. a hospital trust.

APPENDIX 3. SYMBOLS USED ON MEDICAL DEVICES AND THEIR PACKAGING

The following symbols are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the British and European Standard BS EN 980:1997 *Graphical symbols for use in the labelling of medical devices*.

Symbols appearing on medical devices and/or their packaging should not be ignored. If a user does not understand a symbol, they should first look in the Instructions for Use or User Manual for an explanation.

- DO NOT REUSE
Synonyms for this are:
 - Single-use
 - Use only once



- ATTENTION, SEE INSTRUCTIONS FOR USE



- **USE BY DATE** – The symbol is intended to indicate that the device should not be used after the end of the month or day shown.



2002-06-30

- **DATE OF MANUFACTURE**



1999-12

- **BATCH CODE**
Synonyms for this are:
 - Lot number
 - Batch number



ABC 1234

- STERILE



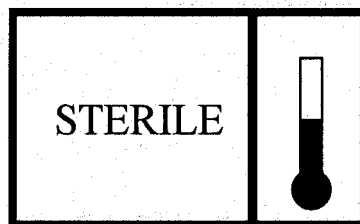
- SYMBOLS FOR 'STERILE' INCLUDING THE METHOD OF STERILIZATION



Method of sterilization:
ethylene oxide



Method of sterilization:
irradiation



Method of sterilization:
steam or dry heat

APPENDIX 4. BIBLIOGRAPHY

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DISTRIBUTION

This Device Bulletin should be brought to the attention of managers and staff in all hospitals, healthcare establishments and others who use single-use medical devices.

The original Device Bulletin DB9501 should be removed from circulation and replaced with this edition.

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