



CSC Guidelines on Reprocessing Instructions for Reusable Medical Devices

Introduction

Devices that are intended for multiple use require processing (or ‘reprocessing’, which may include cleaning, disinfection, packaging and/or sterilization) to ensure that they are safe for reuse. The processing cycle can include a series of steps such as device preparation, disassembly, inspection, pre-cleaning, cleaning, disinfection (thermal and/or chemical), rinsing, drying, packaging, sterilisation (thermal and/or chemical), and storage. The level of processing required varies according to the specific piece of equipment and its intended use and in some cases this may only include simple instructions such as cleaning and routine maintenance, while in other more detailed instructions are required.

It is the responsibility of the device manufacturer to provide detailed instructions to users regarding the safe and effective processing of their devices, when those devices are claimed to be reusable. This is essential to ensure that the devices can be safely reprocessed and reused, to continue to meet their performance specification (as defined by the manufacturer).

This CSC guideline has been developed to assist facilities when obtaining and reviewing reprocessing instructions from manufacturers. The guideline may also be used when considering procurement of devices, including medical, dental, surgical, and temperature-sensitive devices.

Textiles are currently excluded from this guidance document. Further, it is important to note that single-use devices that carry the following label



are not intended to be reprocessed and are therefore also excluded from this guidance.

Note: the specific requirements and recommendations for the handling, cleaning, disinfection, sterilization, drying and transport of any device may vary and be updated by the manufacturer or by certain geographical areas. Reference should be made to any local guidance, standards or instructions as they become available.

Definitions

Device or Medical Device. Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories (including the software intended by its manufacturer), to be used specifically for diagnostic and/or therapeutic purposes.

Note: this definition includes medical, dental and out-patient devices used for surgery or investigations, as well as other devices such as wheelchairs, beds, mattresses, and decontamination equipment (such as washer-disinfectors and sterilizers) with associated cleaning chemistries. For a full definition, refer to the European Medical Device Directive (93/42/EEC). The emphasis in this guideline is on any device that is required to be routinely decontaminated (cleaned, disinfected, and/or sterilized) for the purpose of reuse or safety.

Guideline: A document used to communicate recommended procedures, processes, or usage of particular practice e.g., Health Technical Memoranda (HTMs).

Manufacturer: An organization with the responsibility for the design, manufacture, packaging and labelling of a device in preparation for marketing under its own brand/name, regardless of whether these operations are carried out by that organization or on its behalf by a third party.

Regulation: A rule or order issued by a country, community or administrative agency, generally under authority granted by statute, that enforces or amplifies laws enacted by the legislature and has the force of law.

Standard: A document that specifies the characteristics of a product or material, issued by an organization that develops such documents.

Processing or Reprocessing: activity including cleaning, disinfection and sterilization, necessary to prepare a new or used medical device for its intended use.

Validation: documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications. For example, a validated cleaning process is defined, consistent and performs to a specified level of cleaning (e.g., protein removal)

Regulatory Considerations

The European Medical Device Directive (93/42/EEC) defines the essential requirements for the design, manufacturing and supply of devices and any associated accessories. Such devices (and accessories) must be designed and manufactured in such a way that, when used correctly, they will not compromise the safety of patients, users or other persons. When all applicable essential requirements have been met the device may be placed on the market bearing the CE mark:



Note: Where input from a third party (e.g., a Notified Body) is required as part of the conformity assessment process, the CE marking will also be accompanied by a number identifying the Notified Body involved with the conformity assessment.

One of these essential requirements is that the device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users. Compliance may also be considered when the device manufacturer conforms to relevant national or harmonized standards (e.g., EN or ISO standards) adopted and published in the Official Journal of the European Communities. A relevant harmonized standard has been published that describes the minimum requirement for information to be provided by manufacturers for the processing of reusable devices: BS EN ISO EN 17664: 2004. *Sterilization of medical devices. Information to be provided by the manufacturer for the*

processing of resterilizable medical devices. Although this standard specifically applies to 'resterilizable medical devices', it is a useful and practical reference for all medical devices (including non-critical and semi-critical devices).

CSC Guidance

Device manufacturers should provide at least one detailed set of instructions, including a validated reprocessing method, for each device type/set.

Note: It is not possible to conduct testing and provide customised recommendations reflecting all possible preferences of chemistry type, specific sterilization conditions etc. Manufacturers should include detailed instructions, within the requirements of BS EN ISO 17664: 2004, and highlight specific exclusions or requirements that may be unique for the device type under consideration.

These instructions should include, but are not limited to:

-Manufacturer and contact information

-Device(s), by model number and device description or generic type (allowed by EN 17644)

-Any appropriate warnings, examples include: inappropriate chemicals and/or temperatures and care on handling (e.g. sharp edges).

-Limitations on reprocessing, including any limits on the number of reprocessing cycles. An indication of the expected useful life of the device should be given.

Note: Although expected life of the device may be defined, devices need to be routinely physically examined during normal use/reprocessing to determine whether they continue to be fit for purpose. Accidental damage can occur during use that may compromise the safety and efficacy of the device. Users have a responsibility to ensure there is a local system in place to monitor usage of such devices in order to avoid potential harm to patients or users.

-Instructions on handling at point of use and transport.

Any requirements for handling of the device following patient use, such as: suitable transport containers or chemicals; any precleaning or disassembly; and any limitations on the time recommended between use and reprocessing.

Note: At the time of writing, there is ongoing debate in the UK concerning the risk of patient material (soil) drying on device surfaces. On one hand, the drying of soil on device surfaces can cause damage to the device, making the device more difficult to clean and may pose particular contamination risks (e.g. greater prion resistance to removal). Conversely, when wet devices are transported and stored they may be considered a greater biological hazard to handlers or allow for the overgrowth of bacteria/fungi. Procedures/products may need to be considered that can safely transport devices (to prevent drying) while minimising any potential handling hazards.

-Instructions on preparation for decontamination, including disassembly. This may include physical checks on device integrity (eg. leak testing), removal or disassembly of parts, required manual pre-cleaning and any specific tools needed for that pre-cleaning or device preparation.

-Cleaning instructions: automated (if applicable and preferred) and manual. At a minimum, a validated method of manual cleaning needs to be specified in detail. A validated method of automated cleaning should also be specified, unless the device cannot withstand automated processing. It should be recognized that automated washing is preferred and standard practice in many situations. If automated cleaning cannot be performed, a warning should be provided. Cleaning instructions should include chemical types (e.g., alkaline, acid, neutral, enzymatic etc), cleaning accessories, water quality, temperature range and limits, time or other variables and rinsing techniques (including methods of monitoring chemical residuals and safety limits). Any specific exclusions should be clearly stated. Automated cleaning methods should comply with current EN and/or ISO standards. Consideration may also be given to UK guidelines such as the UK HTMs (Healthcare Technical Memoranda).

Note: at the time of writing the UK HTMs are being consolidated and rewritten (HTM 01 series).

It is not possible for all cleaning chemistries to be tested, given the range of chemistries and cleaning conditions that are used. The most widely used cleaning chemistries are enzymatic and alkaline, although products will vary significantly in cleaning efficacy and compatibility with medical devices. Manufacturers should specifically recommend against types of chemistries considered or expected to be incompatible.

Note: Manufacturers will not provide guidance on where processing should be undertaken and it is the responsibility of the healthcare organisation to have policies in place advising on

decontamination. Users should ensure that appropriate facilities are available, avoiding inappropriate situations such as undertaking manual cleaning in hand washing basins.

-Disinfection.

At a minimum, a validated method of manual disinfection needs to be specified in detail. If this is not required or possible, this should be clearly stated and detailed advice provided on safe use/re-use. A validated method of automated disinfection should be specified, unless the device cannot withstand automated processing. If automated disinfection cannot be performed, a warning to that effect should be provided. Disinfection instructions should include details of:

- thermal and/or chemical disinfection, specified chemical types (eg. peracetic acid or chlorine dioxide formulations);
- disinfection temperatures, contact times and/or chemical concentrations/dilutions;
- any accessories needed;
- water quality;
- rinsing techniques (including methods of monitoring chemical residuals and safety limits).

Automated disinfection methods should comply with EN standards.

Automated disinfection methods should comply with BS EN ISO standards. Consideration may also be given to UK guidelines such as the HTMs and the Department of Health Microbiology Advisory Committee (MAC) Manual for sterilization, disinfection and cleaning of medical equipment.

Note: at the time of writing the UK HTMs are being consolidated and rewritten (HTM 01 series).

If disinfection is the final step for device reprocessing, instructions should be provided on the safe handling and, if applicable, storage of the device prior to patient use.

Thermal disinfection (for example, 90°C for 1-2 mins) is the most widely used method. A variety of chemical-based disinfectants are used as alternatives; these products will vary significantly in disinfection efficacy and compatibility with medical devices. Manufacturers should specifically recommend against the types of chemistries considered, known or expected to be incompatible.

-Drying

A validated drying method should be specified, if applicable (e.g., using High Efficiency Particulate Air (HEPA) cabinets). Drying instructions should include maximum temperatures and recommended exposure times, any accessories required and the use of drying agents (eg. alcohol and other formulations) if applicable.

-Maintenance, Inspection and Testing (e.g., lubrication)

Instruction should include any maintenance (e.g., lubrication, calibration etc), visual (or other) inspection (including mechanical, electrical, cleanliness and dryness, as applicable) and any testing to ensure the safety and functionality of the device. Types of lubricants may need to be specified and shown not to interfere with any subsequent disinfection and/or sterilization methods recommended.

-Packaging (if necessary), in preparation for storage and/or terminal sterilization. If specific packaging materials are provided or required, including packaging considerations to ensure safe handling and/or sterilization of the devices, these should be described.

-Sterilization, when applicable. A validated method of sterilization should be provided. This may include steam sterilization (typically in the UK at 134—137°C for ≥ 3 mins holding time. When steam sterilization is specified, it is recommended that at least one (if not a number of commonly used) steam sterilization process is validated. It is important to note that steam sterilization is a three stage process consisting of air removal, sterilization and drying. Variables can include adequate air removal, steam penetration, vacuum and pressure levels, rates of pressure change, typical drying times under defined conditions etc. If special requirements or criteria are necessary to ensure that the device is adequately steam sterilized outside of typical in-use ranges these should be clearly specified by the manufacturer in the instructions.

Note: although extreme cycles have been recommended in some guidance documents and publications in consideration of prion inactivation, such as 134 °C for 18 mins, it should be clarified with the device manufacturer if these specific cycle conditions are safe for use with the device in question before use.

Other sterilization processes can include high temperature (dry heat) methods and low temperature liquid or gaseous sterilization processes (such as those based on ethylene oxide, hydrogen

peroxide and hydrogen peroxide plasma). These can be safely used when recommended by the device (instrument) manufacturer.

Note: Any accessories required to be sterilized need to be also tested, specified and described.

-Storage

Any specific limitations for the time or conditions of storage of the device prior to use should be described, if required.

A summary of reprocessing instruction requirements is given in Annex A. It is recommended that any references to materials (including chemicals) and equipment used should be generic whenever possible.

Special Considerations

Loan equipment or sets: Individual hospitals or Trusts should have a policy in place regarding the use and reprocessing of loan equipment. When loan equipment or sets are provided sterile from a department applying quality standards, it should not be necessary to repeat any reprocessing prior to clinical use, unless the sterile storage of these devices/sets have been compromised.

Manufacturers should provide instructions for reprocessing, as described in BS EN ISO 17664: 2004 and put particular emphasis on safe handling and transport between hospitals.

Flexible endoscopes: Flexible endoscopes can be complicated medical devices and require close attention to detail to ensure that they are safely reprocessed. Particular attention should be made to ensure that all lumens are identified and can be adequately cleaned-disinfected-rinsed.

Manufacturer's instructions should be detailed, as described above for any medical device.

Prion decontamination: Specific recommendations regarding the reprocessing of medical devices known or at high risk of being contaminated with prions (which are associated with Transmissible Spongiform Encephalopathies such as vCJD and CJD) are currently outside of the scope of this guidance. In the UK, specific recommendations are given and may be periodically updated from the National Institute for Health and Clinical Excellence (NICE; e.g., 2006) and the Engineering and Science Advisory Committee into the decontamination of surgical instruments, including prion removal (ESAC-Pr; e.g., 2007) guidance bodies.

Position regarding reusable devices with no or inadequate reprocessing instructions

Reusable medical devices that are not provided with detailed instructions may not be adequately reprocessed. Whenever possible, concerns should be highlighted to the device manufacturer to ensure safe reprocessing. If specific concerns can not be resolved, the user may consider rejecting requests to reprocess such devices.

References

BS EN ISO 17664:2004. Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices.

ISO/TS 11139:2006. Sterilization of health care products-Vocabulary.

NHS Purchasing and Supplies Agency. Pre-Purchase Questionnaire (June, 2003)

ABHI, 2003. Report on the validation of a reprocessing instructions template for generic Class 1 medical devices.

National Institute Clinical Excellence (NICE). Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures. 2006.

<http://www.nice.org.uk/page.aspx?o=387397> (downloaded January, 2007).

ESAC-Pr. Report from ESAC-Pr: The decontamination of surgical instruments with special attention to the removal of proteins and inactivation of any contaminating human prions. 2007.

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4142318&chk=MU5nKS
(downloaded April, 2007).

Annex A

Template Example of Reprocessing Instructions

Manufacturer:

Devices:

Warnings

Limitations on Reprocessing

Instructions

Point of Use

Transport

Preparation for Decontamination

Cleaning: Manual

Cleaning: Automated

Disinfection: Manual

Disinfection: Automated

 Sterilization

Rinsing

Drying

Inspection and Testing

 Maintenance

 Packaging

 Storage

Criteria for rejecting device for further reuse

Additional Information

Contact Information